School of Pharmacy

Colorectal Cancer Follow-up: An Intervention to Support Patients Following Treatment

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Declaration

To the best of my knowledge and belief, this thesis contains no material previously published by any other person, except where due acknowledgement has been made.

This thesis contains no material that has been accepted for the award of any other degree or diploma in any university.

Signature:

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Date: 08-04-2015

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List of Abbreviations

AIHW	Australian Institute of Health and Welfare
APR	abdominal peritoneal resection
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CRC	colorectal cancer
EORTC	European Organisation for Research and Treatment of Cancer
FRE	Flesch Reading Ease (scale)
GEE	general estimating equation
GP	general practitioner
HRQoL	health-related quality of life
IQR	interquartile range
OR	odds ratio
PBC	perceived behavioural control
PCP	primary care provider
QLQ	Quality of Life Questionnaire
QoL	quality of life
RCT	randomised control trial
SATp	self-assessment tool for patients
SCGH	Sir Charles Gairdner Hospital
SD	standard deviation
SMOG	Simple Measure of Gobbledygook
SPSS	Statistical Package for Social Sciences
STROBE	**St**rengthening the **R**eporting of **Ob**servational studies in **E**pidemiology
TPB	Theory of Planned Behaviour
WA	Western Australia

List of Peer Reviewed Articles Related to this Thesis

Title of Paper*	Journal	Impact Factor	Thesis Chapter
1. Do patients with long-term side effects of cancer treatment benefit from GP support? A literature review	*International Journal of Integrated Care* (Published)	1.261	Chapter 2 (Literature Review)
2. Development of a patient-administered self-assessment tool (SATp) for the follow-up of colorectal cancer patients in general practice	*Quality in Primary Care* (Published)	Not ISI listed	Chapter 3 (Study 1)
3. Predicting attendance of post-treatment cancer care patients in general practice	*American Journal of Health Behaviour* (Published)	1.67	Chapter 4 (Study 2)
4. A trial of a self-assessment tool of problems following treatment of colorectal cancer: A prospective study in Australian primary care	*European Journal of Cancer Care* (Published)	1.31	Chapter 5 (Study 3)
5. Supporting patients treated for colorectal cancer: A video vignette study in general practice	*Journal of Internet Medical Research* (Accepted with minor changes)	4.7	Chapter 6 (Study 4)

* The full citations for these publications are provided in the corresponding chapters of this thesis.

Conference Presentations and Published Abstracts

International Conferences

1. The New Partnerships in Primary Care Cancer Research Conference, Cancer and Primary Care Research International Network Winnipeg, Canada, 10 to 13 June 2014:
   - **Ngune I,** Jiwa M, McManus A, Hughes J. Development and validation of self-administered tool for colorectal cancer patients in general practice. Oral presentation. Abstract published in the *European Journal of Cancer Care 2014; 23:12-1*
   - **Ngune I,** Jiwa M, McManus A, Hughes J, Parsons R, Hodder R. Predicting attendance of post treatment cancer care patients in general practice: The role of concomitant health conditions in the theory of health behaviour. Poster presentation. Abstract published in the *European Journal of Cancer Care 2014; 23:12-2*
2. World Cancer Congress, Melbourne, 3 to 6 December 2014:
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National Conferences

1. Primary Health Care Research Service (PHCRS conference), Australia, Canberra, 22 to 24 July 2014:
   - **Ngune I**, Jiwa M, McManus A, Hughes J. Do concomitant health conditions influence attendance of follow up care for cancer patients in general practice? Poster presentation. Abstract published in the proceedings of the conference.
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Abstract

Due to the growing number of patients being treated for colorectal cancer (CRC), frequent specialist visits will no longer be logistically feasible as a result of the increased number of patients attending busy clinics.[17] Therefore, addressing patients' needs and maintaining continuity of care will require strategies that supplement and support existing services. Various solutions have been explored by hospitals to support cancer patients, such as telephone support, especially following surgery. However, no conclusive evidence demonstrates the long-term outcomes of these solutions for supporting patients.

Most people with CRC are now living beyond five years post treatment and have other chronic conditions for which they visit their general practitioner (GP) on a regular basis.[18] As the survival rate improves, GPs will find that patients with CRC will occupy a larger proportion of their practices, and hence GPs will need additional support. In Australia, GPs are the first point of contact for patients in the health system. Based on these factors, there is potential for GPs to support CRC patients together with ongoing specialist care.

This thesis explores the use of general practice as a setting to support CRC patients in the long term. The purpose of this thesis is to develop and assess the feasibility of a needs-assessment tool (self-assessment tool for patients—SATp) to support patients that seek health advice from their GPs regarding CRC-related health problems. Further, this thesis assesses GPs' approaches to treating common CRC related problems.

The theoretical base for this study was the Glasziou and Haynes model of evidence-based medicine, which outlines the path from research to improved health outcomes. Various techniques were employed to collect data specifically, the Delphi technique, surveys and video vignettes. The data collection instruments included the SATp questionnaire, Theory of Planned Behaviour and internet-based GP questionnaires, as well as review of clinical notes.

The major outcomes of the thesis were as follows:

- The valid needs-assessment measure (SATp) in **Study 1**: The SATp demonstrated internal consistency (Cronbach's alpha 0.70–0.97), readability (reading ease 82.5%) and test–retest reliability (kappa 0.689–1.000). A total of 30 patients piloted the SATp. Participants were on average 69.2 (standard deviation [SD] 9.9) years old, while 26.7 months (range 6–92, median 28) was the median follow-up period at the outpatient cancer clinic. A total of 149 issues associated with CRC treatment were identified by the SATp, with an average of 8.1 needs per patient (median 7; interquartile range [IQR] 3–12.25). The identified needs were in the physical (53, 36%), psychological (53, 36%) and social (48, 32%) domains. The SATp contained 25 questions.

- Trialling of the SATp in **Study 3**: A trial with a cohort of 66 patients with CRC in general practice over a five month period revealed a statistically significant reduction in the number of patient-reported psychological CRC problems. Of the 66 participants who completed this cohort study, 86% visited a GP during the five-month study period. A total of 547 problems were identified (median 7; IQR 3–12.25). Participants with physical problems were more likely to consult their GP ($p = 0.05$) compared to those with social or psychological problems. This trend was demonstrated in participants with diarrhoea (odds ratio [OR] 1.84, 95% confidence interval (CI) 1.05–3.21, $p = 0.03$). The number of problems experienced by participants did not appear to have any influence on the decision to visit a GP. Self-reported psychological problems ($p < 0.01$) significantly reduced over the five-month study period. There were no statistically significant reductions in the number of physical or social problems. GP consultations ($n = 117$) resulted in a total of 78 management actions. Of these, 25 of 78 (32%) were prescriptions, 17 (22%) were investigations and nine (11.5%) were referrals. Prescriptions were mostly for antidepressants (9 of 25, 36%), sedatives (6 of 25, 24%) and analgesics (3 of 25, 12%).

- **Study 2** assessed patients' decisions to seek health advice from a GP about their CRC-related problems. In this study, there were higher patient intentions

to visit a GP for CRC support, especially among those with another chronic illness. Patient attitude (believing their GP has the skills and knowledge to detect a recurrence) and the presence of other comorbidities significantly affected future intention to visit a GP (attitude: $R^2 = 0.233$, $F [1, 65] = 4.345$, $p < 0.01$; comorbidity: $R^2 = 0.128$, $F [1, 65] = 3.019$, $p < 0.05$).

- **Study 4** explored the effect of a variety of clinical and respondent characteristics on GPs' decisions to treat patients with treatment side-effects or symptoms of recurrence of CRC. The results revealed that management by GPs of most CRC-related problems was consistent with expert opinion. In total, 52 GPs consented and 40 (77%) completed the study. Most GPs completed diagnoses of CRC treatment side-effects or symptoms of recurrence that were consistent with the experts' opinions. However, correct diagnosis was dependent on the type of case viewed. Compared to radiation proctitis, GPs were more likely to recognise peripheral neuropathy (OR 12.55, 95% CI 1.38–2.74) and erectile dysfunction (OR 21.98, 95% CI 2.24–36.84) and less likely to identify chemotherapy induced fatigue (OR 0.02, 95% CI 0.09–0.46). GPs who had more hours of direct patient care (OR 8.67, 95% CI 1.23–70.70, p = 0.03) or were experienced in general (OR 9.78, 95% CI 1.18–8.84, p = 0.02] suggested management plans consistent with the expert opinion.

Overall, this thesis has demonstrated that using a screening tool (SATp) with appropriate support in place (general practice) is a viable method to support CRC patients with problems following cancer treatment. The reports of Study 3 showed that GPs can recognise and offer appropriate treatment for most of the side-effects of CRC treatment and for the symptoms of recurrence. However, more training is required for GPs to effectively treat all CRC treatment–related side-effects.

Chapter 1: Introduction

1.1 Background

Colorectal cancer (CRC) is the second most commonly diagnosed adult cancer in Australia.[12-14] From 1980 to 2007, 105,144 people were diagnosed with CRC in Australia, with approximately 12,600 new cases diagnosed each year.[12-14] The number of new cases of all cancers is expected to grow by 319 cases per year.[14] According to age-standardised rates by the Australian Institute of Health and Welfare (AIHW), one in 21 Australians is likely to develop CRC during his or her lifetime, with the risk increasing after 40 years of age, and rising sharply and progressively from the age of 50.[12] The lifetime risk of CRC before the age of 75 years is about one in 17 for males and one in 26 for females, with incidence and mortality increasing progressively with age for both genders.

Improved treatment modalities (surgical techniques and neo-adjuvant therapy) mean that more people with CRC are surviving for longer periods.[15, 16] Based on United States surveillance, epidemiology and end results data for colorectal cancer, it is estimated that the 15-year survival for CRC in that country is 47%.[17] In Australia, there is no uniform national database for CRC survival based on clinical pathological stages.[12] However, the hospital-based register for South Australian teaching hospitals shows a five-year CRC case survival of 88% for Stage A (mucosal and sub-mucosal involvement), 70% for Stage B (muscular involvement), 43% for Stage C (regional nodal involvement) and 7% for Stage D (distance metastases).[12-14] Overall, the five-year survival rate for people treated for CRC in Australia is 89%.[14]

Treatment for CRC includes surgery and, in some cases, chemotherapy and/or radiotherapy. This may result in long-term physical problems, such as bowel dysfunction, urinary problems and neurological deficits.[1, 18] In addition, psychological effects, such as anxiety,[19] depression[7] and fear of recurrence,[1, 20,

[21] plus social problems, such as financial difficulties[22] and activity limitation,[1, 23] may continue to affect patients for many years following treatment.[1, 24-28]

There is evidence that problems related to CRC treatment are not always identified during routine doctor–patient consultations. The reasons for non-identification include patients' reluctance to initiate discussions about these problems, and health professionals' failure to prompt discussion about these issues during a clinical consultation.[29] Consequently, problems may go unresolved and result in delayed diagnosis and treatment. Clinical practice guidelines often recommend that care of patients with CRC must incorporate all aspects of patient care, including physical, psychological and social care; however, this is often not integrated in the follow-up clinical care.[30]

With the significant increase in patients treated for CRC, frequent specialist visits are not logistically feasible due to the sheer number of patients attending a limited number of busy clinics.[31] Therefore, addressing patients' needs and maintaining continuity of care will require strategies that supplement and support existing services. In addition, most people with CRC are now living beyond five years post-treatment and have other chronic conditions for which they visit their general practitioner (GP) on a regular basis.[32] As the survival rate improves, GPs will find that patients with CRC occupy a larger proportion of their practices, and that supporting them is going to become a significant part of their workload. In Australia, GPs are the first point of contact for patients in the health system. Based on this, there is potential for GPs to support CRC patients in conjunction with ongoing specialist care.

One potential solution to address patient problems related to CRC treatment is to assist patients to identify issues as they arise and seek timely help from the clinician (GP) they usually visit for other health conditions. This project provides an insight to this integrated approach through a series of studies that assist patients to identify CRC-related problems and, where appropriate, consult their GP. This project developed a self-administered needs-assessment tool (self-assessment tool for patients—SATp) and offered it to patients post-surgery for CRC to help them monitor their treatment-related problems through consultation with their GP. This

intervention was offered alongside scheduled specialist visits. Further, this project evaluated GPs' management approaches to treating CRC-related problems using standardised patients (actor-patients).

1.2 Research Questions and Intentions

Although problems associated with CRC treatment are documented in the literature, there is a lack of collated information on their management that is easily accessible by patients and clinicians for use in practice.[33] Specifically, there is a paucity of information on general practice, where many people living with CRC are seen occasionally for various reasons. The initial research question of this study emerged from a motivation to outline the most common issues experienced by patients following treatment for CRC, and to provide this information to both clinicians and CRC patients. First, it was important to examine the existing literature and identify these issues:

> **RQ 1. What are the most common problems associated with CRC treatment, as reported in the literature?**

Second, it was essential to examine the current literature to determine whether patients with CRC would benefit from accessing additional support from a GP while still receiving specialist care. The literature provides details regarding the organisation of patient care and flow of information between the specialist and GP. Thus, it was important to explore the literature to assess which issues are routinely addressed during patient visits with a GP and also those that are not routinely addressed. This prompted the second research question:

> **RQ 2. Do patients benefit from involving a GP in their ongoing care following initial cancer treatment?**

After identifying the most common CRC treatment–related problems and examining whether patients benefit from GP support, the subsequent intention of this project was to develop an instrument that could be used by patients to direct

discussions during GP consultation and to provide information to supplement their records. This motivation led to the following questions:

RQ 3. Could a user-friendly, patient completed data collection tool (SATp) be developed to assess problems that patients may experience following treatment for CRC?

RQ 4. Is the SATp a reliable and valid data collection tool for assisting patients to discuss issues associated with their CRC treatment with their GP?

Before testing the SATp, it was important to identify factors that may influence CRC patients' intentions to seek health advice from a GP regarding their treatment-related problems. Most patients with CRC have at least one chronic illness for which they regularly visit their GP.[34] Recent efforts to report patients' preferences for cancer care have indicated that GP support in managing their care is preferred.[35] However, exploration of these preferences has only been in the context of perceived satisfaction with the organisation of the care provided.[36] More evidence is required regarding the role of chronic illnesses and other factors that may influence patients' decisions to attend a GP for CRC health advice. This led to the following research questions:

RQ 5. Are personal attitude, perceived control/barriers and the influence of other people independently associated with CRC patients' intentions to attend a GP for future health advice about their CRC problems?

RQ 6. Do patients' demographics and clinical characteristics, such as the presence of an existing chronic conditions, influence their intentions to visit a GP for health advice about their CRC problems?

After developing the SATp (RQ 3), it was vital to test whether this tool could be used in general practice to identify common issues experienced by patients with

CRC following treatment (RQ 4). This led to the following research questions to test the SATp:

RQ 7. Can the SATp help identify physical, psychological and social problems related to CRC treatment?

RQ 8. If patients present the SATp to their GP, would this facilitate discussions about any physical, psychological and social problems associated with their CRC treatment?

Finally, it was important to assess whether GPs would diagnose and treat the identified CRC treatment–related problems or recurrence. Previous studies have demonstrated that patients consult their GPs during the months and years after treatment for CRC, even for patients with scheduled specialist visits at hospital.[35] In order to address the needs of patients treated for CRC, GPs must be knowledgeable about the recommended treatment for the side-effects of CRC treatment, and the signs and symptoms that merit referral for further specialist treatment. This led to the final research questions:

RQ 9. Can GPs recognise the side-effects of CRC treatment, and the recurrence of CRC?

RQ 10. Can GPs manage the side-effects of CRC treatment and recurrence in accordance with expert opinion?

1.3 Significance of the Project

In Western Australia (WA), follow-up visits with specialists for patients who have received treatment for CRC are scheduled every six months for the first five years post treatment.[31] However, CRC follow-up regimens may vary for each case, depending on patient or clinician preferences, clinical indications, geography and convenience.[31, 37-39] CRC survival is improving; thus, the follow-up workload is continuously increasing and burdening existing specialist services.[31] As such,

more frequent specialist visits for patients may not be feasible due to the increasing number of patients attending outpatient cancer clinics. There is growing recognition that people with CRC have complex physical and psychosocial needs that are not always met in specialist clinics.[40] This is due to workload pressures and/or lack of expertise identifying and managing some of the psychosocial problems that patients present.[41] Given this situation, alternative strategies to support existing specialist services are needed.

GPs are well placed to provide this support because they are the first point of contact in the Australian health system. In most cases, GPs are aware of patients' CRC history before diagnosis because most patients first consult a GP before being referred to the specialist for further treatment.[42] GPs are in an ideal position to support CRC patients following completion of treatment. However, several studies have indicated that survivors of CRC have significant physical, psychological and social problems that are not addressed during regular doctor–patient visits.[43-45] Most patients who have completed cancer treatment are treated as hospital outpatients.[46] In between these outpatient visits, they often consult their GP for further advice.[46] This contact places GPs in a key position, which requires them to have specific knowledge of CRC treatment–related side-effects.[46] However, some GPs do not have access to patients' current clinical information related to their CRC treatment,[47] and sometimes do not have the specific knowledge to identity and treat CRC problems.[48]

The need to support patients and GPs in identifying and discussing CRC treatment–related problems is integral to effective management. The active involvement of patients' GPs following their CRC treatment could enhance continuity of care and patient satisfaction,[49-51] both prerequisites for high quality care. This engagement would also facilitate identification of problems that could be given appropriate attention prior to scheduled specialist visits.

There is evidence that interventions aimed at addressing cancer-related problems (such as telephone support, alongside usual management strategies) may address patient problems following initial surgical treatment.[52] These interventions have also been reported to be effective in addressing cancer patients' problems when

offered alongside specialist visits.[53] Most of these supportive approaches are offered to cancer patients immediately following discharge from hospital, when treatment-related symptoms may be highly distressing.[41] There is evidence that additional support is effective in reducing emergency department presentations of patients with CRC treatment–related problems.[52] To date, most of these additional support interventions have been implemented in a hospital setting and are clinician driven. The sustainability of these supportive interventions may require such initiatives to be patient driven, with measures implemented to assist patients to identify their needs and seek health advice.[53]

This project developed and tested a tailored assessment tool for use by patients with CRC to aid them to identify problems and issues when consulting a GP (SATp). This approach is patient driven and offered alongside specialist visits. Using such a tool may assist clinicians and patients to identify issues of concern that would otherwise be missed during consultations. Overall, the routine, systematic and regular use of a patient-administered assessment tool during general practice may facilitate the timely provision of needs-based care.

1.4 Theoretical Framework Guiding the Development of the Thesis

This thesis was guided by the Glasziou and Haynes model of evidence-based medicine that outlines the path from research to improved health outcomes.[54] According to Glasziou and Haynes, research must be synthesised by:

- framing the research question
- tracking down the best evidence
- critically appraising the evidence for validity, effect and applicability
- integrating the results to be used by clinicians.

Further, Glasziou and Haynes stated that, even with the best evidence available, there are substantial gaps between the evidence and the management patients receive. To achieve better clinical outcomes for patients, clinicians must (i) be aware of, (ii) accept, (iii) apply, (iv) be available and able, (v) act on, (vi) be agreeable to and (vii) adhere to the evidence. However, even with high rates of

transfer of information between these stages, there may be little effect on patient outcomes. Hence, there must be strategies for increased uptake at each stage.

1.4.1 Stages of the Glasziou and Haynes Model

The Glasziou and Haynes model has seven stages being: awareness; acceptance; application; availability; action; agreement and adherence.

1. **Awareness:** Given the plethora of published papers, clinicians may find it difficult to be aware of all relevant and valid information. After identifying the best available evidence, this evidence must be collated and made available to clinicians. This would enable clinicians to locate only relevant information for specific clinical problems.
2. **Acceptance:** While clinicians may have heard of the benefits of the evidence, they may not be persuaded to change management based on this evidence. Hence, more work is needed to identify the methods that can best persuade them.
3. **Applicable:** Even if the evidence is accepted, clinicians and guidelines may not target the correct group of patients.
4. **Available and able:** Undertaking an intervention requires both access and knowledge. For complex interventions, the learning curve is steeper and hence is a greater barrier to changing practice. Clinicians may require additional training before undertaking complex interventions competently.
5. **Act:** Even when people know and accept what to do, they often forget to act on the evidence. Omissions are more frequent for long-term and preventive issues because they are not the pressing focus of a consultation. A reminder is often sufficient for such omissions to be addressed.
6. **Agree:** When clinicians remember to suggest applicable evidence, the above steps may begin all over again for the patient. For patients to agree, they must be aware of the options, accept them and be able to undertake the required action. This may involve a complex mixture of the patients' values and beliefs, which needs to be explored.
7. **Adhere:** Patients must also contend with conflicting advice, adverse effects and sometimes a lack of ability to pay for the tests and treatments. Strategies must be trialled to encourage concordance.

A graphic presentation of the Glasziou and Haynes model of evidence-based medicine is presented in Figure 1.1.

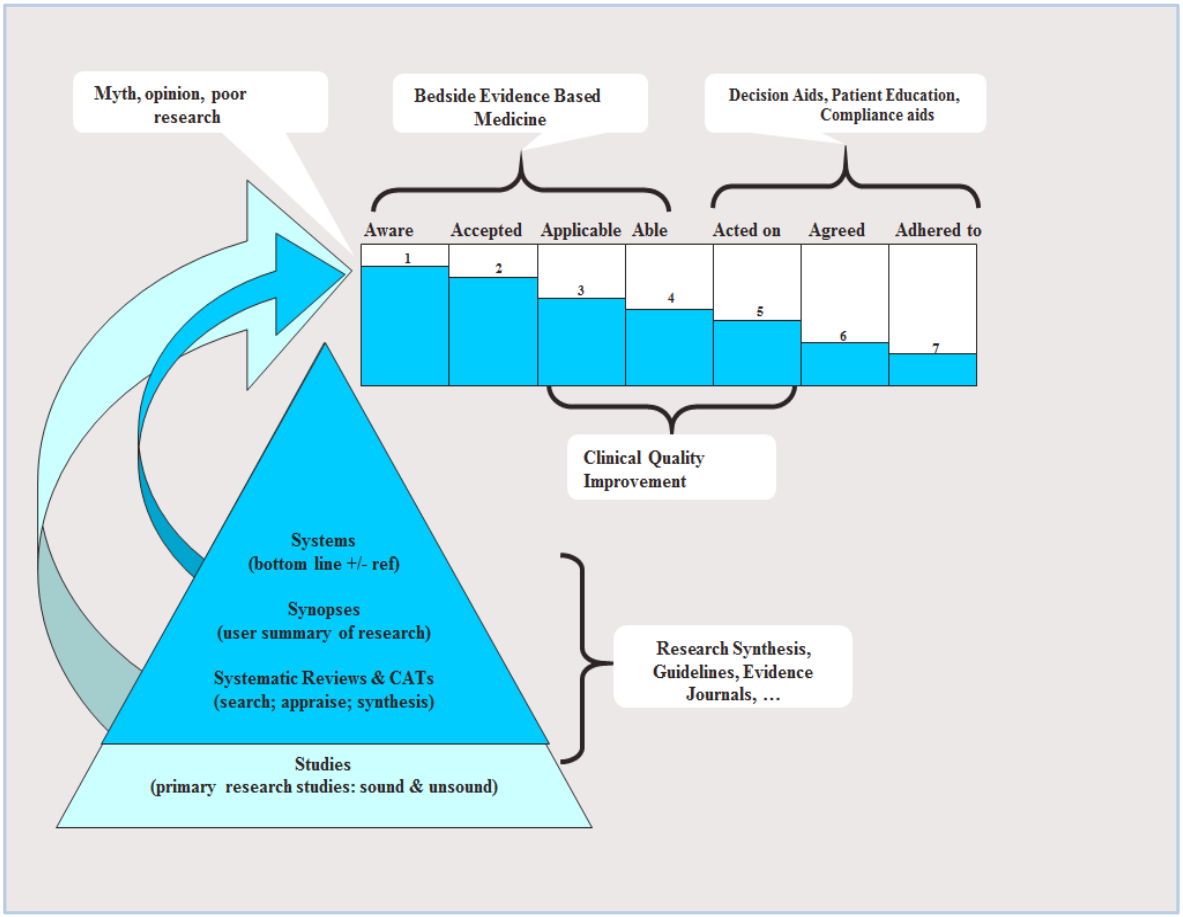


Figure 1.1: Sequential Phases of Paths from Research to Improved Health Outcomes Adapted From Glasziou P, Haynes B. 2005 [54]

In this model, depending on the clinical questions and application, not all stages may be relevant. Thus, this framework is best viewed as an example of 'flexible guidance' for applying evidence-based medicine. Depending on the nature of the intervention, particular stages may be combined or other theoretical models may sometimes be used to reinforce the various stages.

Overall, the design of this thesis sought to:

- critically appraise the available literature to identify problems that patients experience following CRC treatment

- develop a patient-completed needs-assessment tool (i.e. the SATp) based on the identified problems
- apply this tool in a healthcare setting (general practice) to assess its usefulness in identifying and addressing the problems of patients following CRC treatment
- assess GPs' approaches to managing these problems.

The Glasziou and Haynes framework of stages from research to improved health outcomes facilitated the design of this project. Table 1.1 presents a comparison of the Glasziou and Haynes framework and this thesis.

Table 1.1: Overview of Thesis Compared with Glasziou and Haynes Framework

Thesis Chapters	Synopsis	Glasziou and Haynes Framework
Chapter 1	Introduction: Identify scope of the problem and thesis justification.	Research synthesis: Frame the research questions.
Chapter 2	Review of the literature.	Research synthesis: Appraise evidence for validity, effect and applicability.
Chapter 3	Study 1: Develop the SATp.	Awareness: Make the evidence available to clinicians and patients.
Chapter 4	Study 2: Assess factors that influence CRC patients' decisions to visit a GP.	Applicable: Support clinicians to target the correct group of patients. Agree and adhere: Patients must be aware of the options and must accept and be able to undertake the required actions. This may involve a complex mixture of the patients' values and beliefs, which thus needs to be explored.
Chapter 5	Study 3: Trial the SATp in general practice.	Applicable: Support clinicians to target the correct group of patients. Act: Patients should be aware of the options for them to act, and should accept and be able to undertake the options.
Chapter 6	Study 4: Assess GPs' approach to managing CRC problems (video vignette study).	Available and able: Undertaking an intervention requires both access and knowledge. Act: Clinicians must have the ability to use the available evidence to improve patient outcomes.
Chapter 7	Thesis discussion and conclusions.	All stages of the Glasziou and Haynes Framework

1.5 Overview of Thesis Chapters and Study Method

This thesis is presented in seven chapters, as follows.

Chapter 1 discusses the research background, questions and intentions, significance of the study, and theoretical frameworks guiding the development of the study.

Chapter 2 presents a review of the literature relating to CRC as a public health problem. The problems experienced by patients following CRC treatment are also reviewed. Finally, the importance of GPs' support of and involvement in patient care following CRC treatment is reviewed.

Chapter 3 outlines the steps involved in developing a self-assessment tool for CRC patients (SATp) (**Study 1**). The study's aims, methodology, results and findings are discussed. The primary aim of Study 1 was to develop a patient-completed needs-screening tool to identify physical, psychological and social needs among patients treated for CRC. The existing literature was evaluated to identity problems experienced by patients with CRC post-treatment. Through a series of validation processes, a list of common problems experienced by patients following treatment was generated and tested for its reliability and ability to identify common problems experienced by CRC patients. Study 1 employed a Delphi method[55] as the conceptual framework to validate the questionnaire.

A purposive sample of 17 panellists (patients with CRC and health professionals involved in CRC follow-up care) was invited to validate the questions to be included in the SATp. The researcher sent out the draft SATp to consenting experts via email for them to provide their level of agreement with each item using a Likert scale on a questionnaire developed for this purpose. The researcher coordinated the responses of the panel of experts until a consensus of 70% was achieved. The developed questionnaire was pre-tested for reliability and usability by a group of 30 consenting patients with CRC. The result of Study 1 was a 25-item questionnaire—the SATp that was deployed in Chapter 5 of this thesis.

Chapter 4 presents the study participants' intentions to visit a GP (**Study 2**). It details the factors that may influence patients' decisions to seek health advice from their GP. The study design, methodology and results are presented. Study 2 was a cross-sectional study that employed a questionnaire based on the theory of planned behaviour (TPB). The TPB outlines three constructs (personal attitudes, social norms and perceived barriers and controls) that influence a person's intention to perform a certain action.[56] In this study, the influence of TPB constructs on patients' decisions to seek health advice from a GP was assessed. Further, the role of clinical and respondent characteristics on the TPB constructs was explored.

A convenience sample of 66 patients was recruited from an outpatient cancer centre of Sir Charles Gairdner Hospital (SCGH)—a tertiary referral teaching hospital located in Perth, Western Australia. The consenting participants were invited to complete a demographic survey and the TPB questionnaire. The TPB questions were adapted from various cancer studies,[57-62] and validated via the process outlined in a manual on constructing questionnaires based on the TPB.[62] These questions were then piloted by a group of five patients to assess for readability, as the assembled items were from various studies conducted in different countries. A regression analysis of the collected data was computed to identify predictors of participants' intentions to seek health advice from a GP about CRC-related problems

Chapter 5 describes trialling the SATp in general practice (**Study 3**)—the SATp intervention. The study design, methods and findings are discussed. The main aims of Study 3 were to test whether the SATp developed in Study 1 would identify physical, psychological and social problems related to CRC treatment, and whether SATp-identified problems would be addressed in a GP consultation.

A convenience sample of 66 participants (recruited in Study 2) was invited to participate in a prospective study. At the beginning of the study, the participants were asked to nominate their regular GP, who was then contacted and advised that the patient was participating in the study and that a researcher had consent to access their records and survey their GP. The participants were provided with a booklet of

SATp questionnaires (developed in Study 1), which they completed at six time points (at the baseline and then monthly for five months). The participants were also invited to take the booklet whenever they consulted their GP.

At the end of the study follow-up period (at five months), the clinical notes (integrated notes) were reviewed by a team of trained researchers. Data from the clinical notes were extracted using a data abstraction pro-forma developed for this purpose. The data were analysed using the generalised estimating equation model (logistic regression) to control for the correlations between the responses on multiple responses from each participant.

Chapter 6 describes GPs' approach to managing the problems experienced by patients following CRC treatment (**Study 4**). This was a video vignette study. This chapter presents the study design, methods and results. The primary aim of Study 4 was to assess the factors that affect GPs' decisions to treat patients with CRC-related problems or symptoms of recurrence.

Participants were recruited from a convenience sample of 100 GPs across Australia who were members of the Curtin Health Innovation Research Network. The video vignettes were acted from six scenarios developed by panel of experts, who were selected based on their expertise in the follow-up of CRC patients. These scenarios were developed through a Delphi method. The experts viewed the vignettes and outlined the management of such cases and the relevant physical examination they would undertake if reviewing such a case. For each vignette, clear indications for specific management—including referral, prescription, reassurance and/or investigation—were requested. The survey was administered via web-based software (https://www.qualtrics.com/) approved by Curtin University. The six video vignettes were presented to each participant. The data were analysed using the generalised estimating equation model (logistic regression) to control for correlations between the responses on multiple vignettes from each participant.

Chapter 7 discusses the issues pertaining to the findings from all three studies (Studies 2, 3 and 4). Recommendations related to the study findings and areas for further research are identified, and conclusions are drawn.

Figure 1.2 presents a graphical illustration of the organisation of the thesis chapters.

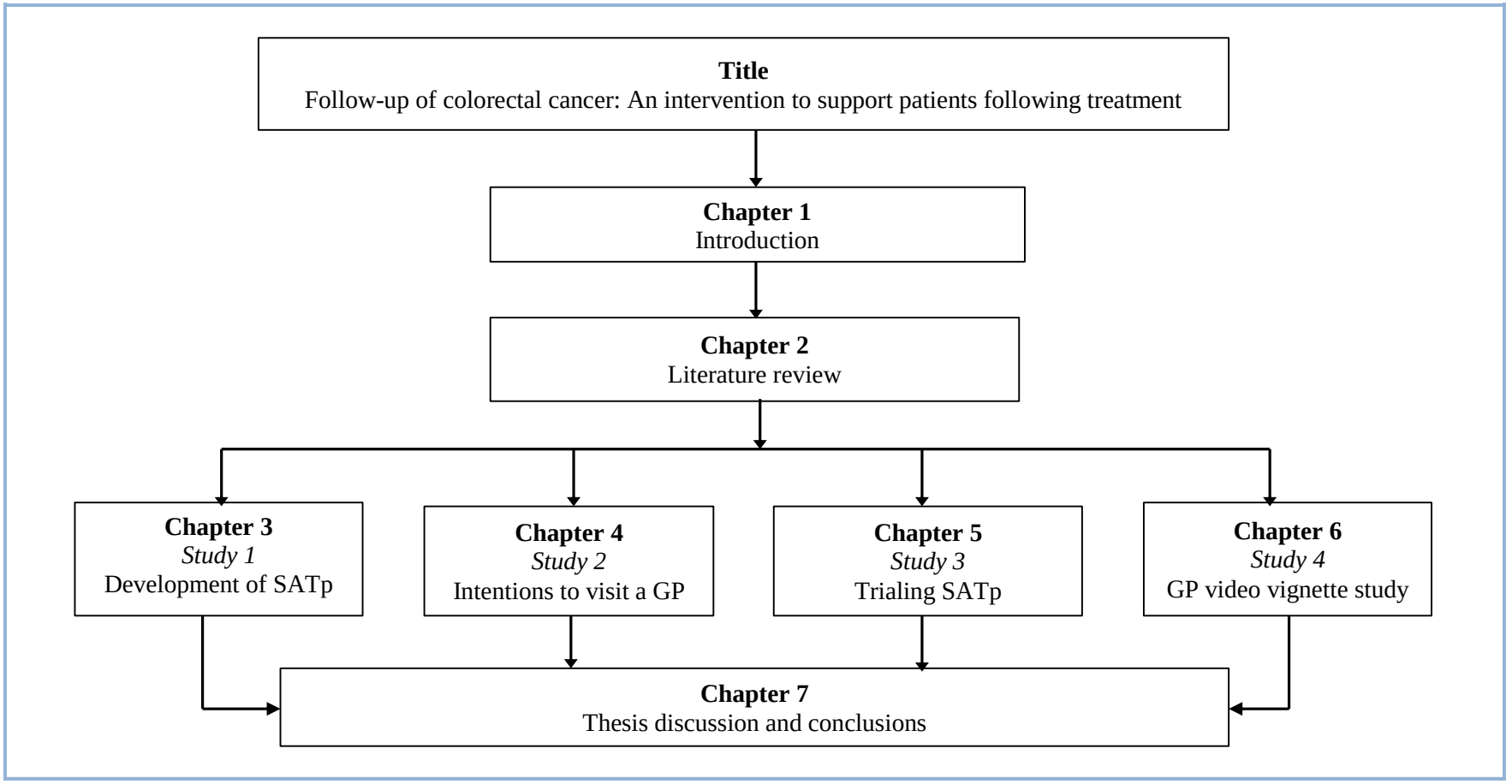


Figure 1.2: Schematic Presentation of the Thesis

Chapter 2: Literature Review

This chapter presents the epidemiological perspective of CRC. Further, this chapter summarises the various treatment modalities for CRC, including surgery, chemotherapy and radiotherapy. It also discusses the range of adverse issues experienced by patients following treatment. The remainder of the chapter describes the benefits patients may derive by having a GP involved in their care following treatment.

2.1 CRC: General Epidemiology

CRC is a major health burden worldwide. Internationally, 1.2 million people were expected to be diagnosed with bowel cancer in 2007, making it the fourth most common cancer in the world that year. A comparison of the United States, the United Kingdom and Australia shows that CRC is ranked in the top four most frequently occurring cancers,[14, 63, 64] highlighting the significant effect of this cancer in these populations.

In Australia, CRC was the second most common cancer diagnosed and the second most common cause of cancer death between 2006 and 2010.[14] By 2007, 105,144 people had been diagnosed with CRC during the previous 26 years, and, each year, there are approximately 12,600 newly diagnosed cases of CRC and 4,700 deaths directly related to this cancer.[65] The number of new cases of cancer is expected to grow by 3,090 cases per year. The greatest increase in cancers is projected for prostate cancer (939 extra cases per year), followed by melanoma of the skin (392), CRC (319), breast cancer (314) and lung cancer (190).[65]

CRC is the most common cancer diagnosis in patients older than 75 years.[66] More than 90% of invasive CRCs are diagnosed in patients older than 50 years, with 67% being diagnosed in patients older than 65 years. In these cases, both genders are equally affected by this disease; however, there is a higher incidence among males over 50 years than among females.[7]

Clinical pathological staging/classification is currently the most important determinant of prognosis, and is widely used to classify CRC.[38, 67-69] The Australian classification (Australian Clinical Pathological Staging [ACPS]) is comparable to the Tumour, Node, Metastasis classification of the American Joint Committee on Cancer and the Union for International Cancer Control (UICC) Fifth Edition (UICC stage)[68] that is currently recommended for daily routine use and for use in clinical trials.[70] Table 2.1 shows the descriptors of clinical pathological staging and how they relate to each other. This thesis uses the UICC stage descriptor.

Table 2.1: Various Clinical Pathological Staging for Colorectal Cancer

ACPS[38]	**UICC Stage UICC—Fifth Edition[68]**	**Tumour, Node, Metastasis[68]**
A0 + A	Stage I	T1, T2, N0, M0
B	Stage II	T3, N0, M0 T4, N0, M0
C	Stage III	T1, T2, N1, M0 T3, T4 N1, M0 Any, N2, M0
D	Stage IV	Any T, any N, M1

T1: tumour invades submucosa; T2: tumour invades muscularis propria; T3: tumour invades through muscularis propria into subserosa or into non-peritonealised pericolic or perirectal tissues; T4: tumour directly invades other organs or structures and/or perforates visceral peritoneum.[68]

2.2 CRC Survival

Due to early diagnosis and treatment for CRC (surgery, chemotherapy and radiotherapy), overall survival rates have improved from 48.0 to 66.2% during the last two decades.[71] Population-based studies show that approximately 50% of CRC cases are diagnosed while the cancer is still confined to the primary site (Stages I, II and III), while the rest of patients are diagnosed when the cancer has spread (Stage IV).[70-72]

The survival rates are dependent on the stage of the disease. Patients with Stage I can be expected to have a five-year relative survival of 80 to 95%, Stage II of 60 to 80%, Stage III of 30 to 55%, and Stage IV of < 3%, as defined by the UICC five-year stage-specific survival rates.[68] In ACPS, hospital-based registries for teaching hospitals in some states show that the five-year CRC case survival varies with ACPS: 88% for

Stage A, 70% for Stage B, 43% for Stage C (regional nodal involvement) and 7% for Stage D (distance metastases)[14]—see Figure 2.1.

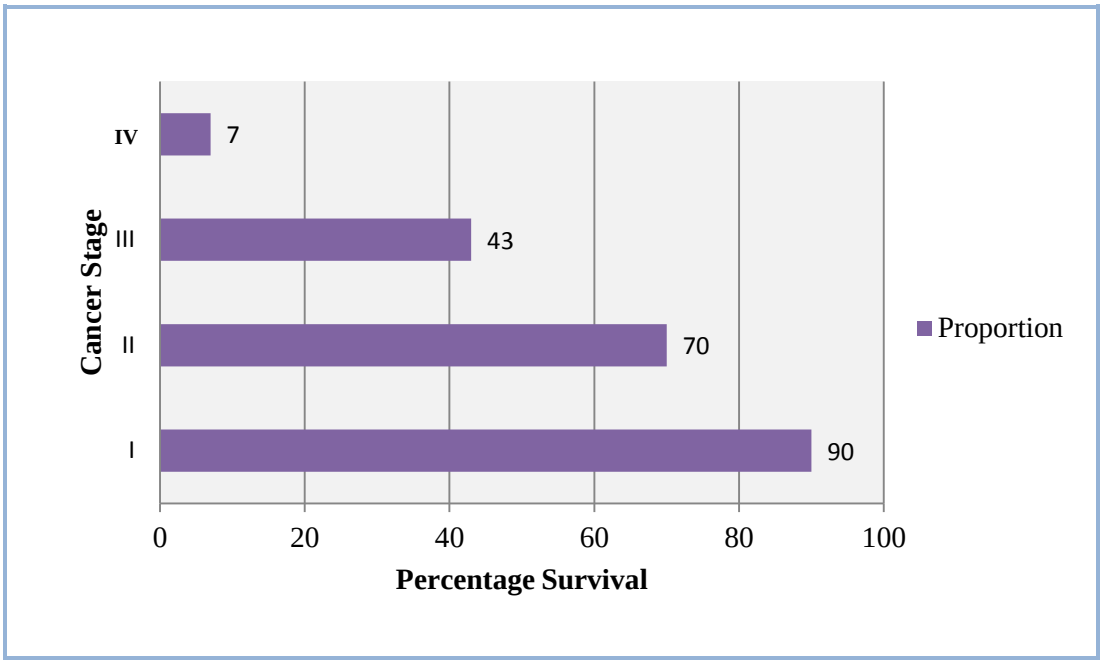


Figure 2.1: Five-year CRC Case Survival by ACPS[14]

Although survival rates are dependent on the stage of the cancer, significant differences have been observed among patients operated on as emergencies and those treated as elective cases. Emergency surgery for CRC is associated with a high postoperative morbidity and mortality, and both short- and long-term survival are impaired.[73]

The increase in the use of chemotherapeutic agents to treat CRC—such as fluorouracil and a combination of this agent with others, such as leucovorin and folinic acid—during the last decade has showed a 10% reduction in the risk of death and an increase of 2.3% in the five-year survival rate.[71] Sequential exposure of patients to combinations of fluorouracil, irinotecan and oxaliplatin is documented to extend median overall survival by approximately 20 months.[74]

Similarly, the incidence of recurrence is dependent on the stage of the disease. In the 1990s, of the two thirds of patients undergoing resection with curative intent at the time of initial diagnosis, about 30 to 50% would relapse and die of their disease.[75] However, current trends show that recurrence and mortality rates have reduced. For

example, five-year follow-up data from the Swedish Rectal Cancer Trial of patients treated with preoperative irradiation show a 4% recurrence rate in Stage I disease, 10% in Stage II and 20% in Stage III for rectal cancer patients.[76] While early detection and improved treatment of CRC have led to more people surviving for longer periods,[14, 16] many survivors of CRC live with long-term side-effects of treatment, which affects their quality of life (QoL).[14]

2.3 Management of CRC

2.3.1 Overview of Cancer Management

Managing colon and rectal cancers is somewhat similar because surgery is the primary mode of treatment for localised disease (Stages I to III CRC) for both cancers.[37, 38, 67, 70, 77] Approximately 98% of patients with CRC undergo surgery.[18, 38, 78-84] Due to the increased risk of local recurrence, the management of rectal cancer varies to that of colon cancer.[18, 38, 79, 81, 82, 85] Differences include surgical technique, the use of radiation therapy, and the method of chemotherapy administration.[18, 38, 79, 81, 82, 85] For rectal cancers in Stage I at low risk (< 3 cm, < 30% circumference of the bowel, moderately or well differentiated, localised), local excision is usually indicated. However, for Stage I at high risk (not fulfilling the low-risk criteria), surgical resection and preoperative radiotherapy are offered. For Stage II to III rectal cancers, surgical resection, preoperative chemo-radiotherapy and postoperative chemotherapy are the standard treatments.[38] For patients with colon cancer who are surgical candidates, treatment entails surgical resection and postoperative chemo-radiotherapy.[38] Using adjuvant chemotherapy as a standard treatment for all patients with Stage II colon cancer is debated;[86-89] however, certain subgroups in this stage that are at higher risk of recurrence (including those with bowel obstruction, lymphovascular or perineural invasion, perforation, or tumours that have abnormal DNA content) and who may benefit from adjuvant therapy should be considered for chemotherapy.[38, 90-93]

Although radiotherapy has a limited role in colon cancer,[38, 67, 94] chemo-radiotherapy is used for Stage I and II rectal cancer and in all cases of Stage III colon and rectal cancers[2, 38, 67, 90, 95, 96] because there are added survival benefits.[88, 92, 97] In some cases, chemo-radiation is used for Stage I rectal tumours with lymph node positivity

(19.6 %).[98] Overall, at least 20% of patients at Stage II and 70% at Stage III receive chemotherapy.[71, 97]

2.3.1.1 Surgical Management

The main aim of surgical treatment for CRC is to excise the tumour and its margin and surrounding tissue (resection), which may contain cancer cells that pose a risk to patients.[99, 100] Surgery significantly minimises the risk of cancer recurrence and is a major curative treatment option. The type of surgery performed for colon cancer is largely dependent on where the cancer is located in the bowel. For example, a right hemi-colectomy is performed for cancers of the caecum, ascending colon or hepatic flexure; a left hemi-colectomy for transverse, splenic flexure descending colon cancers; and a sigmoid colectomy for cancer of the sigmoid. For colon cancer, the most recent advancement in surgical treatment is the development of laparoscopic-assisted or keyhole surgery. Meta-analytic evidence confirms that laparoscopy has comparable recurrence and survival rates to open surgery.[77]

For rectal cancers, surgical treatment historically involved formation of a colostomy (part of the colon is brought out of the abdominal wall to allow passage of faecal matter), which is still indicated today for all abdominal peritoneal resection (APR). APR is an extensive surgical procedure that involves removal of the anus, the rectum, part of the sigmoid colon and the regional lymph nodes through incisions to the abdomen and perineum.[79] APR is reserved for cancers typically found in the lower third segment of the rectum.[79, 100] Other surgical procedures for rectal cancer include anterior resections, which preserve the sphincter.[100] The type of resection is determined by where the malignancy is found in the rectum. For example, high anterior resection is indicated for tumours in the recto-sigmoid, and low anterior resections for those in the upper, middle or lower segments.[79, 100] For ultra-low or low anterior resection, a temporary ileostomy (part of the small bowel is brought to surface of the abdomen, bypassing the rectum) is performed to allow the anastomosis to heal.[79]

2.3.1.2 Neo-adjuvant Therapy and Adjuvant Therapy

Neo-adjuvant therapy can be defined as any treatment given before a first treatment (such as surgery or radiotherapy) for a primary tumour, when the first treatment was aimed at completely eradicating all visible tumour.[79] When such treatment is offered post–primary treatment, it is referred to as 'adjuvant therapy'.[79]

In addition to surgery, chemotherapy and radiotherapy can be administered to treat CRC. Chemotherapy and radiotherapy are usually indicated for people with more advanced disease. For patients with Stage III colon cancer, chemotherapy—usually a combination of CapeOx (Capecitabine and oxaliplatin), FOLFOX (5-FU, leucovorin, and oxaliplatin) are indicated to be administered post-operatively.[38, 85] For patients with Stage II colon cancer, chemotherapy is not usually offered, and guidelines recommend that clinicians and patients should discuss the relative merits of this. Radiotherapy is generally not required for colon cancer and is limited to patients with specific disease characteristics.[38, 94] For rectal cancer, radiotherapy is recommended in preoperative or postoperative setting for Stage II tumours.[38, 94] Evidence exists that radiotherapy reduces the risk of local recurrence and, when offered post-operatively, shrinks the tumour and lowers the incidence of long-term morbidity.[38, 94]

2.4 Effects of CRC Treatment: A Review of Literature

2.4.1 Overview of Treatment Side-effects

While treatment has added survival benefits, a myriad of associated side-effects may affect the patient's QoL. Normally, the acute effects diminish after completion of treatment; however, some symptoms persist even years after therapy. Although issues and symptoms are most prominent during the first three years, the effects of treatment can persist long after this, and include fatigue, sleep difficulty, fear of recurrence, anxiety, depression, negative body image, sensory neuropathy, gastrointestinal problems, urinary incontinence, and sexual dysfunction.[1, 20] Estimates from a population-based study by Schneider et al.[3] show that the most commonly reported symptoms are fatigue (23%), negative feelings about body appearance (14%), diarrhoea (13%) and constipation (7%). In this study, higher percentages of

respondents attributed health effects to cancer or its treatment, including worries about health (24%), physical discomfort (19%) and activity limitations (15%).[3]

2.4.2 Aims of the Review

The aims of this literature review were to describe the long-term effects of CRC following treatment, and outline the implications of these CRC treatment effects.

2.4.3 Methods

2.4.3.1 Search Strategy

A search strategy was developed to electronically source studies published in English from four academic databases: PubMed/Medline, CINAHL, Web of Science and Cochrane Reviews/Trials. These were searched in January 2013 by employing the following strategy using medical subject headings:

1. colorectal cancer (MH) OR bowel cancer (MH) AND
2. *side-effects as topic (MH) OR needs as topic (MH) OR quality of life* (MH) AND
3. treatment (MH)
4. randomised control trial (MH)
5. *projects (MH)
6. various combinations (1 AND 2, 1 AND 3 AND 4, 1 AND 5, 2 AND 3, 2 AND 4, and 2 AND 5).

2.4.3.2 Eligibility of Studies, and Outcomes Assessed

For inclusion, studies had to describe CRC or have CRC among the cancers being described. Studies that included CRC, regardless of the site or stage of the disease, were eligible for review. All studies that outlined the needs assessment for cancer in which CRC was included were integrated in the review. A total of 3,218 references with relevant titles were identified. These were complemented by a search of grey literature sourced from both the Curtin University library catalogue and the AIHW website. Eight references were found using this latter strategy. All duplicates (2,018)

and articles without full-text versions (550) were removed, yielding a total of 650 references.

The titles and abstracts of the 650 references were independently reviewed by two reviewers (IN and MJ) using the selected inclusion criteria, from which 69 studies were included for the review (Figure 2.3). Studies that had been evaluated by the included systematic reviews were not reconsidered for critical evaluation in this review of literature. However, the main findings of these systematic reviews were considered for this literature review. Details of other studies that were not assessed by identified systematic reviews have been outlined in Appendix 2:1. The literature reviewed suggested that physical, psychological and social problems should be considered when assessing patients who have completed CRC treatment.[101]

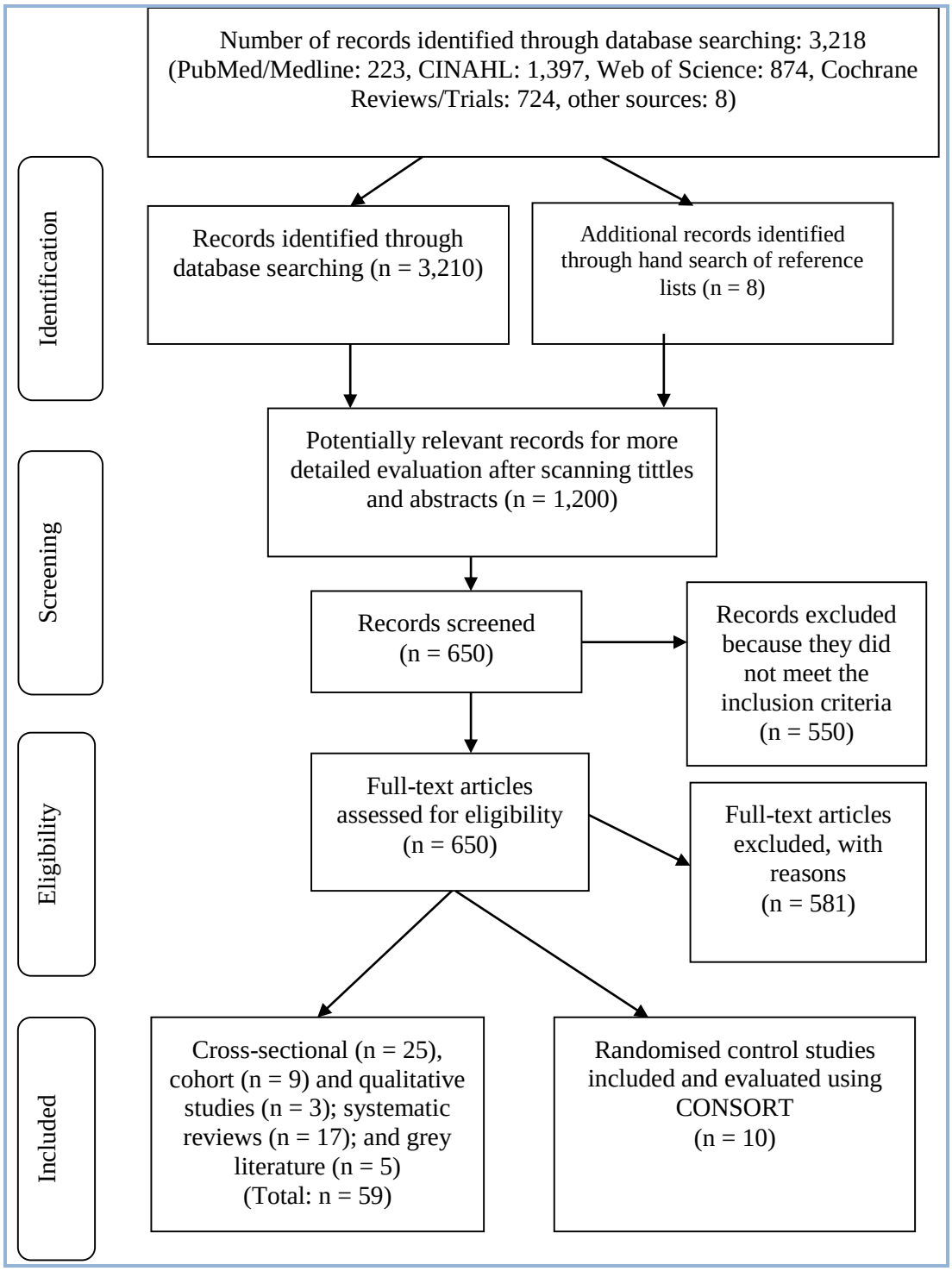


Figure 2.2: Flow Diagram of the Results of a Literature Review of CRC Treatment Effects

2.4.4 Results

2.4.4.1 Physical Effects

Physical side-effects of treatment relating to the bowel, the urinary bladder, sexual dysfunction, peripheral neuropathy and fatigue were reported by 50 of the 69 papers. Long-term bowel and urinary problems, such as impaired continence and increased urgency, were more common among those who had invasive surgery, such as total mesorectal excision,[18, 78, 79, 81-83] with rectal cancer,[18, 78, 79, 81-83] and those treated with adjuvant radiotherapy.[70, 86, 102-106]

Functional bowel problems caused by reduced storage capacity of the bowel and adjuvant treatment—such as frequent and incomplete bowel movements, abdominal pain, urgency, leakage and incontinence, constipation, diarrhoea and flatus[1, 3]—were reported as long-term effects. Studies that examined these outcomes showed that approximately 20% of patients who received chemo-radiation continued to experience increased bowel movements per day, with 20 to 30% reporting some form of incontinence and the inability to defer bowel movement.[1, 3] Additionally, patients with a permanent or temporary stoma reported several ostomy issues, such as prolapse, skin-related problems, leakage or stenosis of stoma opening.[4, 6, 38, 107] Patients who received radiation followed by APR reported urinary dysfunction, such as urinary incontinence (38%), difficulties in bladder emptying (31%), the need to void within two hours of voiding (70%) and the use of continence aids (57%) up to five years after treatment completion.[1, 108]

In a cohort study examining the long-term effects (40 months) of chemo-radiation between survivors of rectal cancer who had and had not received chemo-radiotherapy, in the group that received chemotherapy, only nine of 41 patients (22%) had less than four bowel movements per day, while 15 (37%) had five bowel movements per day and 17 (42%) reported clustering - (numerous bowel movements over a few hours) ($p < 0.001$). Compared to the non-radiation group, of those who received chemo-radiotherapy, 19 (46%, $p < 0.001$) needed to wake at night to pass a bowel movement, 16 (39%) reported occasional incontinence, 7 (17%) reported frequent incontinence, 17 wore a pad (41%, $p < 0.001$) and 17 (41%, $p < 0.001$) reported perianal skin irritation.[106]

Other physical symptoms identified in this review included sexual dysfunction, peripheral neuropathy, loss of weight and abdominal pain.[1, 109] Sexual dysfunction was reported as both a physical and psychological effect.[1, 110] In both cases, sexual dysfunction was associated with the effects of surgery, adjuvant therapy or indirectly to the psychological effects of a stoma that may cause negative body image.[6, 8] Patients with a stoma reported psychosocial issues, such as fear of leakage, concerns about appearance, odour, negative body image, smell, impotence and decreased libido.[6, 8] One study reported that 43% of sexually active men with CRC and 69% of men overall have International Index of Erectile Function scores that are considered abnormal.[6, 8] Similarly, 39% of sexually active women and 62% of all women respondents in this study had Female Sexual Function Index scores that were considered abnormal,[6, 8] despite the fact that nerve-sparing surgery was used routinely.[6] Overall, 26% of the bowel cancer patients continued to report at least one form of sexual dysfunction three years after treatment.[1]

Approximately 92% of patients offered adjuvant chemotherapy (oxaliplatin and infusional 5-fluororuacil [FOLFOX] or bolus 5-fluorouracil [FLOX]) develop some degree of sensory neuropathy,[111] with 8 to 12% developing Grade 3 neuropathy (severe neuropathy interfering with function—defined as being severe enough to interfere with daily living) and 22% requiring premature discontinuation of oxaliplatin for severe neuropathy.[111] The acute nerve effects reduce within one month of treatment discontinuation; however, the median time for resolving these symptoms is approximately nine months.[10] Although only 1% of patients have residual Grade 3 neuropathy at 12 months after completing therapy, approximately 20% of survivors may experience worsening of symptoms after treatment discontinuation, and up to 12% have persistent symptoms for four years after completing adjuvant treatment, when all grades are combined.[1]

2.4.4.2 Psychological and Social Effects

The psychological effects of treatment—such as anxiety,[19] depression,[7] fear of recurrence [21] and fatigue [1, 5, 20, 112, 113]—are commonly reported many years after diagnosis. Estimates from a population-based study by Schneider et al. showed that

the most commonly reported symptoms three years after diagnosis are fatigue (23%), negative feelings about body appearance (14%), worries about health (24%), physical discomfort (19%) and activity limitations (15%).[3] Other studies that describe the long-term psychological effects of CRC indicate that 26 to 44% of long-term survivors continue to worry about cancer recurrence, and 48% have sleep difficulties.[9] Similar high rates of 68% have been reported by other studies that assessed the long-term effects of CRC treatment.[114]

Some studies included in this review reported health concerns linked to anxiety and depression, with 24% of patients showing depression scores high enough to require evaluation for clinical depression.[1] Other reports showed that both the anxiety and depression subscales of the Hospital Anxiety and Depression Scale significantly predicted QoL scores.[110] Long-term (more than one year) negative feelings about body appearance are more common among stoma survivors than non-stoma survivors. Up to four years after treatment, 25% of stoma patients report negative body image.

Social factors such as financial problems,[22] information needs,[115] activity limitation and social function issues[1, 23] have also been reported by patients years after treatment completion. Social function and activity limitation among stoma patients can be negatively affected up to one year after diagnosis; however, the presence of a permanent stoma has a minimal effect on social and activity functioning two years after diagnosis.[1, 23] Stoma patients complain of more financial difficulties than do non-stoma patients. A 2005 cross-sectional study by Sideris et al that compared the effect of a permanent colostomy on the QoL of patients who underwent operations for low rectal cancer showed that stoma patients have more financial difficulties than do non-stoma patients.[23] Additional studies included in this review demonstrated that gastrointestinal cancer survivors, including CRC, are at a higher risk of unemployment than are healthy adults (48.8 v. 33.4%).[116]

2.4.5 Implications of CRC Treatment Effects

The implications of treatment effects are that people have multiple and unique sets of needs that require holistic management. This includes clinical, social and psychological needs related to treatment, as described above, and other co-occurring

chronic illnesses. Given that the median age for CRC is 69 years, more than 30% of this group have an existing chronic illness[117] that requires ongoing management. Meeting patients' needs is a central tenet to the delivery of quality healthcare, and clinicians who are the most accessible to CRC patients on a regular basis must be involved in the management of these patients. The following section explores the potential for GPs' involvement in the management of these problems.

2.5 Benefits of Involving a GP Following Cancer Care: A Literature Review

2.5.1 Overview of GP Involvement in the Care of Cancer Patients Following Treatment

Due to the improved survival rates of cancer patients following treatment, greater attention needs to paid to the ongoing physical and psychosocial needs of this population.[65] Long-term physical problems and psychological morbidity—such as anxiety,[19] depression[7, 118] and fear of recurrence,[21] and social factors,[1, 20] such as financial problems[22] and activity limitation[1, 23]—continue to affect patients for many years following treatment.

Cancer patients are now living longer, and many have coexisting health conditions.[34, 119] For example, around 50% of people with CRC are now living beyond 10 years after treatment[32] and between 30 to 60% of CRC survivors aged 70 years or older have other concomitant health conditions and are more likely to die of other causes.[117] As the survival rate of cancer patients improves, GPs will find that these people occupy a larger proportion of their practice. In addition, with the increasing number of cancer patients accessing specialist cancer clinics, strategies that supplement these services will be required to support patients with long-term treatment side-effects.

In Australia, cancer patients attend a GP for multiple reasons,[34] including for care of health conditions and to receive preventive health services, such as screening, health promotion advice and vaccinations.[120] Given that GP services are a cornerstone of the Australian health system, there is potential for GPs to support cancer patients with

ongoing specialist care. Moreover, there is evidence that cancer patients first present to a GP with cancer-related side-effects or symptoms of recurrence, even when receiving ongoing management from a specialist.[35] There is empirical evidence that a GP-led follow-up model for cancer patients would be ideal; however, oncologists must still play a fundamental role in managing these patients.[121] Studies have shown that cancer patients who are supported by both oncologists and GPs receive better preventive healthcare and cancer care than do those who are managed by either of the specialties independently.[120] In addition, some patients still value access to specialist services, especially during the early stages after treatment.[121]

To date, most of the literature reviews that report on interventions provided by a GP concurrent with a specialist only provide details regarding the organisation of patient care and flow of information between the specialist and GP.[122-125] Although these reviews offer recommendations regarding communication between the GP and specialist,[122-125] patients' outcome data regarding the issues addressed during patient visits with the GP are limited.[123] Given these findings and the potential benefits of support that patients may receive by having a GP involved in their cancer care, this study conducted a literature review to assess the care of patients in the context of ongoing specialist care, with particular reference to GP involvement. This review focused on all types of cancer studies that met the inclusion criteria, thereby assessing integrated approaches to care for multiple cancer types.

2.5.2 Aims of the Review

The aims of this literature review were to:

1. describe the proactive management of patients with long-term needs following cancer treatment, including surveillance for recurrence;
2. describe the effectiveness of GP support in post-treatment cancer care;
3. critically appraise these studies.

2.5.3 Methods

2.5.3.1 Search Strategy

A search strategy was developed to electronically source studies published in English from six academic databases: AustHealth, CINAHL, the Cochrane Online Library Reviews/Trials, Embase, PHCRIS and PubMed/Medline. These were searched in January 2014 employing the following strategy using medical subject headings:

1. family practice (MH) OR primary health care (MH) or general practice AND
2. parallel care as topic (MH) OR shared care as topic (MH) OR cancer follow up* care (MH) AND
3. evaluation research (MH)
4. randomised control trial (MH)
5. feasibility projects (MH)
6. various combinations (1 AND 2, 1 AND 3 AND 4, 1 AND 5, 2 AND 3, 2 AND 4 and 2 AND 5).

2.5.3.2 Eligibility of Studies, Types of Participants and Outcomes Assessed

For inclusion, studies had to describe delivery of interventions by a GP, and care had to be delivered alongside specialist care. Studies that included adult cancer patients, regardless of the site or stage of the disease, were also eligible for review. For inclusion in the review, patients should have completed treatment for cancer. Given that terms such as ‘shared care’, ‘complementary care’ and ‘parallel care’ were poorly standardised in the taxonomy and nomenclature of the electronic databases, the search strategy was kept as broad as possible. All papers with such terms were included for the review. The cancer follow-up phase was poorly defined regarding when this period began; hence, all studies in which patients had completed the indicated treatment were included in the review.

2.5.3.3 Identification of Studies

A total of 1,802 papers were identified from the six academic databases: AustHealth (n = 202), CINAHL (n = 500), the Cochrane Library Reviews/Trials (n = 200), Embase

(n = 368), PHCRIS (n = 132) and PubMed/Medline (n = 410). Potentially relevant titles and abstracts of 533 references were reviewed using the following inclusion criteria:

1. the study represents a research article (rather than a letter or commentary)
2. the research context is primary care—that is, settings in which health practitioners are primary health physicians, family practice doctors or GPs
3. the primary focus is to describe interventions or evaluate care provided by a GP alongside hospital care for patients who have completed cancer treatment.

The primary researcher author (IN) and two other reviewers (MJ and AM) independently reviewed 143 studies. Studies that included other models of post-treatment cancer care were excluded. In total, 20 studies were eligible to be included in the review (Figure 2.3).

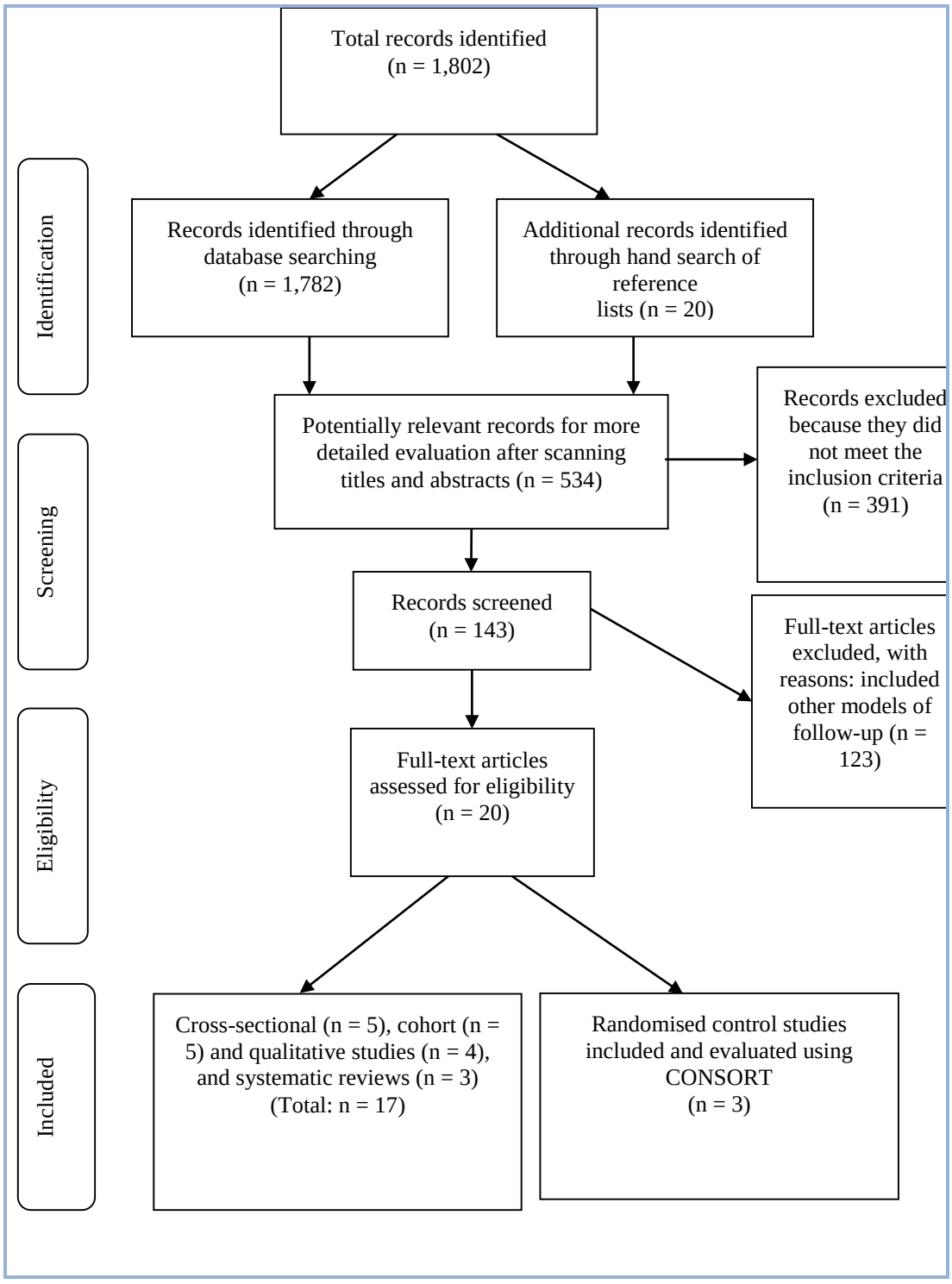


Figure 2.3: Flow Diagram of the Results of a Literature Review of GP-led Supportive Care Interventions

2.5.3.4 Data Extraction

One reviewer (IN) extracted articles and assessed the methodological quality of the studies using Consolidated Standards of Reporting Trials (CONSORT)[126] for randomised control trials (RCTs), **St**rengthening the **R**eporting of **Ob**servational Studies in **E**pidemiology (STROBE) [127] for cohort and cross-sectional studies, and Walsh and Downe criteria[128] for qualitative studies.

CONSORT is an evidence-based, minimum set of recommendations for reporting RCTs. It offers a standard way for authors to prepare reports of trial findings, thereby facilitating their complete and transparent reporting and aiding their critical appraisal and interpretation. The CONSORT statement comprises a 25-item checklist, with the items focusing on reporting how the trial was designed, analysed and interpreted.[126] See Appendix 2.3.

STROBE is an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of strengthening the reporting of observational studies in epidemiology. STROBE offers a standard way to report study design, results and interpretation of cohort, case control and cross-sectional studies. The checklist comprises 20 items that offer a basis for evaluating observational studies.[127] See Appendix 2.4.

The Walsh and Downie recommendations are a set of iterative criteria that create a working framework for qualitative research appraisal. This checklist comprises eight stages that aid with critical appraisal of study designs, methodology, interpretation and transferability of results.[128] See Appendix 2.5. Selected articles were also reviewed by two other researchers (MJ and AM) as a measure of inter-rater reliability. Differences in assessments by the reviewers were resolved by consensus when the full-text articles were reviewed. The intervention, outcome details and main conclusions were collected on a standard data sheet that included the type of study, author, data, sample size and participation rates (see Appendix 2.1).

2.5.4 Results

The reviewers reached consensus on the remaining 20 articles, all of which were included in the review (Figure 2.3). There were three RCTs, five cohort studies, five cross-sectional studies, four qualitative studies and three systematic reviews. Due to variation in the studies' methodology and how the findings were reported and analysed, a meta-analysis was not feasible even for studies with similar outcome measures. Additionally, all studies included in this review were conducted in different countries with very different healthcare arrangements. The results of these studies are summarised in Appendix 2.1.

2.5.4.1 Interventions and Evaluation of GP Involvement

Studies in which an intervention occurred or was evaluated are described below. In summary, 10 studies were based on a framework that sought information from patients about the rehabilitation care (psychological, physical and social care) provided by their GP. Patients' rehabilitation needs were either assessed directly by the GP or by cancer nurses or specialists, and then relayed to the GP in a letter.

1. In the Bergholdt et al. study, patients were invited to participate in an interview about their rehabilitation needs with a rehabilitation coordinator at the hospital. The information from the hospital was sent to the GP about patients' individual needs for rehabilitation, and the GP was encouraged to contact the patients to offer support with rehabilitation.[36]

2. In the Holtedahl et al. study, cancer patients were invited to a 30-minute consultation with their GP, who was asked to let the patients discuss their experiences as cancer patients, and to tell the patients explicitly that they would be welcome to contact the GP whenever they had a question or problem related to their disease. [42]

3. Two studies described a shared care programme between the GP and specialist. In Nielsen et al.'s study, a discharge summary letter detailing patients' physical, psychological and social problems was posted to the GP. The summary also

contained information about what the oncologists expected the GP to do; specific information about each patient's type of cancer, treatment plans and prognosis; and general information about treating common side-effects and pain. The names and telephone numbers of the doctors and nurses responsible for the patient were also attached.[46] In the Hall et al. study, patients were asked to attend GPs for follow-up appointments. Follow-up protocols and a system of specialist support were sent to the GPs by the treating specialist. The GPs were given an opportunity to shadow specialists as they conducted follow-up appointments at the hospital.[41]

4. In the Sisler et al. study, cancer survivors who had a GP were sent a survey assessing the patients' perceptions of continuity of care around the time of discharge from the cancer centre. Health-related QoL (HRQol) was also assessed as long-term patients stated they had seen a GP during their survivorship care.[129]

5. Bowman et al. assessed primary care provider (PCP) involvement in key activities measured by cancer survivors' reports. It examined whether PCPs discussed cancer-related problems with patients, and whether these discussions resulted in tests and procedures.[130]

6. In five other studies, patients completed a survey or data were analysed on one of the following: the number of visits to the family physician during the prior year; the family physician's, specialist's and oncology team's responsibility for cancer care; the family physician's involvement in cancer care; the perceived family physician's actual and expected roles in various aspects of care (coordination, psychosocial support, information transmission, symptom relief and preventive health); and the family physician's pattern of care.[50, 131-134]

The results of the type of GP involvement in cancer care are summarised in Appendix 2.2.

2.5.4.2 Critical Appraisal of the Studies

2.5.4.2.1 Recruitment, Randomisation and Methods

Three RCTs with GP interventions were identified.[36, 42, 46] All three studies fulfilled at least 22 of the 25 items in CONSORT and provided background details about the study objectives, eligible participants and outcomes of interest. Reporting of the randomisation process was generally poor, with details of the allocation concealment not fully provided. Strategies used to generate allocation sequences were only fully described by Bergholdt et al.[36] and Holtedahl et al.[42] A critical appraisal of the studies is presented in Appendix 2.3.

Of the five cohort and four cross-sectional studies, none fulfilled all criteria of the STROBE statement.[128] Seven studies[129, 131-136] provided clear information regarding the participants' eligibility criteria, study setting, locations and relevant dates, including periods of recruitment. In all nine studies, descriptions of the study methods were often sparse or were either missing or only partially satisfied. A critical appraisal of these studies is presented in Appendix 2.4. For the four qualitative studies,[41, 130, 137, 138] nearly all criteria outlined by Walsh and Downe[128] were met. The studies were contextualised with the existing literature, the details of the methods/design were consistent with research intent, and the data collection strategies were apparent and appropriate. The authors also provided data to support interpretation and elements of study relevance and transferability. However, the descriptions of the analytical approach in these studies were unclear. They were missing details of how the subjective meanings of participants were portrayed and handled, and in what ways the deviant data were sought. A critical appraisal of the studies is presented in Appendix 2.5.

2.5.4.3 Overview of Research Findings

The outcomes and results of the type of interventions are summarised in Table 1 for RCTs and cohort and cross-sectional studies. The following two main themes emerged when the data were synthesised:

1. Care outcomes were generally reported as any progress in patients' psychosocial and physical functioning (or an overall improvement in patients'

QoL), detection of recurrence, management of comorbidities and preventive health.

2. Perspectives of care were reported as patients' satisfaction with the care provided by the GP, or health professionals' views of the GPs' role in providing post-treatment care.

2.5.4.3.1 Physical and Psychological Outcomes and QoL

Six studies reported GPs' supportive role in providing post-treatment cancer care in the context of ongoing specialist care.[36, 41, 42, 46, 132] There were mixed results reported regarding the QoL benefits to patients. In a randomised control trial investigating whether patients benefit from contact with a GP after cancer treatment, Holtedahl et al.[42] showed no significant effect of GPs' involvement for the 81 patients who answered two sets of QoL questionnaires. However, there was a significant improvement at six months in physical and social function status ($p = 0.032$, and 0.004, respectively); when frequent contact occurred.

Bergholdt et al.[36] examined the involvement of GPs in cancer rehabilitation, with the primary outcome being the global health status of patients after six months. They allocated 281 patients to the intervention group and 297 to the control group (hospital care only), and found that the intervention had no statistically significant effect on the primary outcome. Adjustment for age and gender showed results similar to the unadjusted analysis. Overall, this intervention had a limited effect on the QoL and psychological distress of patients, but had a positive effect on patients' evaluation of cooperation between primary and secondary healthcare sectors.[36] A quality analysis of this study based on CONSORT revealed an adequate sample size. Although this study was powered (80%, $\dot{\alpha} = 0.05$, $n = 144$) to detect the differences between the groups in terms of the primary outcome, process evaluation measures—such as GP proactivity and patient participation—were not undertaken, which may have affected the QoL results. To improve the QoL outcome, Bergholdt et al.[36] recommended the development of screening tools that support identification of patients with special needs, and initiatives that support GPs to undertake a proactive role for patients with cancer needs.[36]

Nielsen et al.[46] reported similar results to Bergholdt et al.[36] In this study, a discharge summary letter detailing patients' potential or current physical, psychological and social problems was sent to the GP at the end of the treatment period by the oncologists. Patients in the intervention group were encouraged to visit their GP. Patients' attitudes towards healthcare services, reports about contact with the GP, HRQoL and performance status were evaluated at the baseline and then three and six months later. The results of patients' assessments of their HRQoL using the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30 measure showed no statistically significant differences between the intervention and control groups; however, there were improvements in the quality of care offered in the intervention group.[46]

2.5.4.3.2 Preventive Health and Management of Other Chronic Illnesses

In a retrospective cohort study, Earle analysed chronic comorbidities and preventive healthcare of cancer patients managed by both primary care physicians and specialists. In this study, 50% of survivors (7,465 patients) continued to see an oncologist during follow-up, and 8% of those (587 patients) saw only an oncologist. In all categories of care, patients who were supported by both oncologists and primary care physicians received the highest proportion of recommended care for the management of cancer, chronic illness and preventive health, followed by patients who were supported by primary care physicians. Patients who were supported only by oncologists received significantly worse preventive care than did patients who also had a primary care physician. Survivors who did not receive care from an oncologist were less likely to undergo the cancer-related procedures of surveillance colonoscopy (27.6 v. 46.7%) and mammography (26.5 v. 31.3%) compared to patients who saw an oncologist. Conversely, the subset of patients who were seen only by primary care physicians were more likely to receive influenza vaccination (55.2 v. 43.6%), cervical screening (14.7 v. 8.2%) and bone densitometry (3.9 v. 1.1%) than were patients who were supported only by an oncologist.[139]

In an analysis by Haggstrom et al. of the type of doctor specialist most frequently visited by cancer patients during follow-up care (other than an oncologist), 16% (n = 303) reported visiting a GP. Of these, 70% had two or three other medical conditions

followed up in primary care.[50] In this study, survivors were asked whether they received follow-up medical tests to check for signs of other health conditions, and whether their doctor discussed preventive health issues, such as lifestyle changes, diet and exercise. The results of this study indicated that survivors of CRC who most often saw oncologists were still significantly more likely than those who saw PCPs to report seeing a doctor for follow-up tests, and less likely to receive a physical exam. In terms of health promotion activities, CRC survivors who most often saw primary care physicians for follow-up cancer care were significantly more likely than survivors who saw specialists to report that their follow-up doctor helped with lifestyle (83 v. 63%, p = 0.015) and discussed diet (70 v. 48%, p = 0.005). In models adjusting for patient characteristics, oncologists were significantly less likely than PCPs to discuss disease prevention, provide help with lifestyle and discuss diet.[50]

Anvik et al. (2006) explored the role of the GP in the post-treatment cancer care of patients recently treated, and reported that patients trusted their GP to provide competent care, especially when they had more complex healthcare needs in addition to cancer.[140]

2.5.4.3.3 Perspectives of Care: Patients' Perspectives

Satisfaction with care was reported both qualitatively and quantitatively in six studies.[41, 42, 46, 130, 137, 140] Holtedahl et al.[42] reported that there was a non-significant tendency towards higher satisfaction among patients whose GPs were involved in their care. The improvement in scores for perceptions of patients regarding their overall cancer care was evident between randomisation and six months (score from 55.2 to 58.9, p = 0.060). Further, when the authors conducted a subgroup analysis comparing those patients treated with curative intent and those offered palliative treatment, this tendency was confirmed for patients treated with curative intent (62.15 v. 46.38, p = 0.035).[42]

In an analysis by Aubin et al.[132] of patients' perceived gap between actual and expected family physician involvement in cancer care during all phases of cancer, patients preferred their family doctor to be involved in all aspects of care.[132] Nielsen et al.[46] reported a statistically significant difference between intervention and control

groups at three months when patients' attitudes towards cooperation (between GP and oncologist) and their feeling of 'not being left in limbo' were assessed (p = 0.025). A subgroup analysis of these variables showed that men in the GP-integrated programme felt less 'left in limbo' (p = 0.031), as did the younger age group (18 to 49 years) at both three and six months (p = 0.024 and p = 0.031).[46] In this study, being male (p = 0.007) or younger (p = 0.029) were predictors of increased contact visits with a GP and of the ability of the GP to manage post-treatment cancer care.

Qualitative studies also reported comparable results. Hall et al.[41] modelled a shared care model and explored the views of potential patients and the opinions and experiences of patients and doctors in the model,[41] while Hudson et al. explored survivor preferences of the shared care model.[137] Hall et al.[41] and Hudson et al.[41] revealed that patients were more receptive to GP involvement in post-treatment cancer care if they were confident that the GP had received extra training and support from the hospital.[137] The shared care model was also seen as favourable to participants because of reduced waiting time and parking fees. In particular, this model was reported to be valuable to those living in regional areas because of the reduced number of hospital visits and travel logistics.[41]

Five studies reported continued patient contact with a GP while patients were undergoing follow-up at their hospital.[46, 50, 131, 132] Aubin et al.,[132] Bowman et al.[130] and Lundstrom et al.[135] assessed family physician involvement in cancer care and found that large proportions (88%, 62% and 35%, respectively) of patients continued to visit their GP informally throughout their cancer journey, despite being supported in the hospital by a specialist. Similarly, Nielsen et al.[46] noted that patients randomised to the shared care group had an increased number of visits to their GP at three and six months (p = 0.049 and p = 0.042, respectively).

2.5.4.3.4 Health Professionals' Perspectives

Three studies[41, 133, 140] in this review evaluated health professionals' views and experiences of GP involvement in post-treatment cancer care. In a survey of oncologists and GPs, Forsythe et al. examined perceptions of shared responsibility for the psychological follow-up of cancer patients.[133] In this study, GPs were more likely

to report shared provision for the management of physical symptoms and sole provision for health promotion and psychosocial care, compared to oncologists. In contrast, oncologists reported a shared approach for provision of patient psychosocial care ($p < 0.001$). Among the aspects of psychosocial care provided by GPs were treatment of sexual dysfunction, depression and anxiety.[133] Similarly, Wind et al.[141] explored the experiences of surgeons addressing cancer-related psychosocial problems and other non-cancer-related physical problems and reported that over 40% of surgeons felt that these issues were beyond their field of experience.

Wind et al.[141] and Anvik et al.[140] reported that both GPs and surgeons are confident that GPs can handle post-treatment cancer care among patients with a low risk of recurrence ($p = 0.004$)[141] and that GPs have a role in the follow-up of many patients with cancer, including during initial phase after treatment.[140] In a qualitative study exploring GPs' and patients' experiences and opinions of GP involvement in post-treatment care, Hall et al. found that GPs felt that their own clinical skills were improved when they received support and training.[41] In this study, the clinical skills of GPs were enhanced by attending training seminars and shadowing specialists at cancer clinics.[41]

2.6 Discussion and Conclusion

This review of the literature reported the outcomes of GP involvement in post-treatment care alongside hospital care for cancer. Nearly all reviewed studies indicated that involving GPs in the care of patients alongside specialist visits is possible and acceptable to patients. Emerging evidence suggests that it is feasible to involve GPs in the care of cancer patients, provided that GPs are equipped with the necessary skills.

This review indicated that both specialists and GPs were confident that GPs are able to assume a role in post-treatment cancer care. Most GPs are prepared to undertake a more prominent role in post-treatment cancer, contingent on good specialist support. The reviewed studies showed no differences between the GP and specialist in managing patients' physical health, and GPs were more skilled at recognising psychosocial issues. Patient contact with the GP for supportive care was significantly

associated with identification and management of psychosocial issues. Overall, GPs reported greater involvement in the management of psychosocial issues, and shared management with specialists for physical symptoms.

There were various results from the studies that examined QoL, with some studies reporting non–statistically significant improvements in patients' QoL, and vice versa. Overall, GP involvement in follow-up care was associated with improvement in the physical and social wellbeing of patients following cancer treatment. In studies in which GP follow-up did not result in statistically significant improvement in QoL, patients reported enhanced quality and coordination of care. Patients who had their GP involved and had other concomitant health conditions reported greater continuity of care and a less fragmented approach to managing their health.

However, caution should be exercised when interpreting these results because the study periods were relatively short in some of the reports, the measures used to assess QoL were different, and the reporting quality of each study was variable. For all studies, there were many aspects of methodological quality identified. Overall, regarding QoL, the quality of data was generally poor and no conclusive evidence can be drawn from the collated data or narratives. In addition, given that not all studies included in this review performed a subgroup analysis on the effect of GP involvement for patient outcomes with different types of cancer, it is plausible that the effects may differ if this model was applied to specific cancers. Most studies reported an overall effect of GP involvement patient on outcomes (physical, psychological and social) for all cancers combined.

The reviewed studies did not provide strong evidence of the patient's role in driving the delivery of care. Most studies either mentioned patient proactive approaches as a recommendation in their summary of findings or in the methodology. In some studies, patients were encouraged to visit their GP if they perceived a need to do so, and, in others, the GP was provided an assessment of the patient's condition and encouraged to invite the patient for a consultation. The quality of measures used to aid GP consultation was not standardised. In some studies, GPs used broad questions to assess the general wellbeing of the patient, while, in others, the nurse coordinator assessed the needs of the patients, sent the report to the GP and encouraged the GP to contact

the patients. The deployment of a validated questionnaire detailing the possible needs of the patients and how this assessment was used to encourage a consultation with the GP was limited. Bergholdt et al.[36] recommended using a screening tool or decision support tool to identify and address patient needs.

2.6.1 Study Strengths and Limitations

The small number of studies identified for this review may arise from a variety of reasons. The ongoing involvement of GPs in post-treatment cancer care is not clearly described in the literature. In some cases, this was described as 'formal' shared care, in which the different roles of the GP and specialist were clearly delineated, while other studies described this as 'informal' shared care, in which patients continued to visit their GP informally, while still attending scheduled visits with a specialist. However, database searches were supplemented by a hand search from the list of references of the identified papers and systematic reviews. Finally, the heterogeneity of the study methods, outcome measures and analytical approach of various studies meant that no data could be pooled in a meta-analysis.

2.6.2 Recommendations

To improve patient outcomes in this approach, it would be helpful to design and test validated measures that support identifying patients who may benefit from GP involvement while still receiving ongoing care from a specialist. Additionally, it is useful to consider devising and deploying initiatives that encourage and facilitate patients to first consult their GP about what they believe are their needs or symptoms of recurrence. Applying this model of post-treatment cancer care to patients with a specified cancer would clarify whether the outcomes would be different.

This review of the literature demonstrates that GP involvement alongside specialist care for cancer patients has not been robustly explored, despite some studies concluding that this is feasible and acceptable to patients. Therefore, the following two chapters explore the development and application of a patient-completed assessment tool—an initiative that encourages and facilitates patients to consult their GP regarding post-treatment cancer care.

Chapter 3: Developing the SATp for use by CRC Patients in General Practice (Study 1)

A paper describing the study in this chapter has been accepted for publication in the journal *Quality in Primary Care*:

> Ngune I, Jiwa M, McManus A, Parsons R, Hodder R, Entriken F. Development of a patient-administered self-assessment tool (SATp) for follow-up of CRC patients in general practice. Qual Prim Care. 2015.

Details of the letter of acceptance are shown in Appendix 3.6.

This chapter outlines the steps involved in developing a self-assessment tool for CRC patients (SATp) to help them to articulate problems associated with their CRC treatment post-surgery.

3.1 Summary

Background: Treatment for CRC may result in physical, social and psychological issues that affect patients' post-treatment QoL. A comprehensive assessment conducted to identify these needs noted a lack of tools and processes available in general practice to facilitate identification and discussion of patients' problems post–CRC treatment with a GP.

Aims: The aim of Study 1 was to develop a patient-completed needs-screening tool (SATp) that identifies the potentially unmet physical, psychological and social needs of patients treated for CRC.

Methods: The development of the SATp included a review of the literature; ensuring face and content validity with reference to an expert panel; psychometric testing, including readability, internal consistency and test–retest reliability; and ensuring usability in clinical practice.

Results: The SATp contained 25 questions. It indicated internal consistency (Cronbach's alpha 0.70–0.97), readability (reading ease 82.5%) and test–retest reliability (kappa 0.689–1.000). A total of 30 patients piloted the SATp. Participants were an average of 69.2 (SD 9.9) years old, while 26.7 months (range 6–92, median 28) was the median follow-up period at the outpatient cancer clinic. A total of 149 issues associated with CRC treatment were identified by SATp, with an average of 8.1 needs per patient (median 7, IQR [3–12.25]). Identified needs were in the physical (53, 36%), psychological (53, 36%) and social (48, 32%) domains.

Conclusions: The SATp is a reliable and valid self-assessment tool that is useful for identifying CRC patient needs. Further testing of this tool for validity and usability is outlined in Chapter 5—Study 3.

3.2 Summary Statement

3.2.1 What Do We Know?

The following knowledge was used as the basis of this study:

- the treatment for CRC often results in long-term side-effects
- assessment of CRC-related needs and side-effects is important in determining ongoing care for CRC patients
- the available needs-assessment tools do not adequately capture long-term CRC side-effects
- there is no documented CRC needs-assessment tool used in general practice to assess the long-term side-effects of treatment.

3.2.2 Contributions of Study 1

This study reports the development of a reliable and valid needs-assessment tool (SATp) that is specific to examining CRC and the long-term side-effects of its treatment.

3.3 Background

Treatment for CRC is associated with physical, social and psychological side-effects that can affect patients' QoL many years after completing treatment. Although acute side-effects diminish after treatment completion, some problems persist for years, including fatigue, sleep difficulty, fear of recurrence, anxiety, depression, negative body image, activity limitation, sensory neuropathy, gastrointestinal problems, urinary complications and sexual dysfunction.[1, 3] There is evidence that these problems are not always identified during routine doctor–patient consultations. The reasons for non-identification include patients' reluctance to initiate a discussion about their needs, and health professionals' failure to prompt patients to discuss these needs during consultation.[29] Consequently, issues may go unchecked, thereby resulting in delayed diagnosis or treatment.

Regular assessment of CRC-related needs and treatment side-effects has recently received attention as being important in the ongoing management of patients.[142] Assessing and attending to patients' needs are important steps towards effective patient-centred care, with failure to manage these needs appropriately having the potential to adversely affect QoL.[143] A standardised screening tool that identifies common physical, psychological and social issues could facilitate consultation between patients and health professionals to address these needs.[144]

Many instruments assessing the physical and psychosocial side-effects of cancer treatment are available, including the Supportive Care Needs Survey,[145] EORTC PR29,[101] Supportive Needs Screening Tool[29] and Cancer Survivors' Unmet Needs measure.[143] Some items measured by these questionnaires are relevant to general cancer problems, while others are not specific to CRC. Cancer patients' needs vary depending on the type of cancer and the clinical/pathological stage of disease. For example, the needs of Stage IV cancer patients differ greatly from those with Stages I to III.[3, 143] Moreover, these tools have not been integrated into primary care practice. This study reports the development of a patient-administered needs-assessment tool (SATp) to guide CRC patients to identify their care needs.

3.4 Objectives

The primary aim of Study 1 was to develop a patient-completed needs-screening tool (SaTp) that identifies the physical, psychological and social needs of patients treated for CRC.

3.4.1 Sub-objectives

The sub-objectives of Study 1 were:

- to critically evaluate the existing literature to identity problems experienced by CRC patients following CRC treatment
- through a series of validation processes, to generate a list of common problems experienced by patients following treatment
- to pilot the agreed list to test its reliability and ability to identify common problems experienced by CRC patients.

3.5 Structural Framework

The structure of the SATp is based on a framework by Pigott et al.[29] and Bonevski et al.[145] that suggests that seven criteria should be used to determine the effectiveness of needs-screening tools in cancer follow-up care. The SATp has several properties. This tool:

- contains integrated physical, psychological and social aspects to measure multiple domains of CRC care; these domains have also been adopted by Jiwa et al.[146] in a needs assessment for breast cancer patients
- uses a self-reporting approach to facilitate direct and comprehensive assessment of subjective health needs
- measures the needs in a defined temporal context—questions relate to needs experienced in the previous four weeks; as advocated by the Pigott et al. study, the timeframes used should be useful for clinicians to develop a clear understanding of patients' needs
- demonstrates validity and reliability through expert review, test–retest and pilot testing to provide a sound basis for comparison

- embraces a user-friendly response framework, such as yes/no responses, to simplify the questions for the patient and prompts for the clinician to probe further
- contains only 25 items and is system-friendly by minimising the patient and staff time required to complete and review
- provides an opportunity for clinicians to link patients to services—this tool is meant to be a guide during consultations in order to assist a thorough exploration of possible issues.

3.6 Methodology

3.6.1 Study Design

This study used a Delphi methodology to develop a patient self-completed needs-screening tool to identify potentially unmet physical, psychological and social needs among CRC patients. A Delphi study technique solicits the opinions of experts through a series of carefully designed questionnaires that are interspersed with information and opinion feedback in order to establish a convergence of opinion.[55]

The Delphi method was developed in the 1950s and was originally used to forecast the effect of technology on warfare.[147] The method entails a group of experts who anonymously reply to a questionnaire and subsequently receive feedback in the form of a statistical representation of the 'group response', after which the process is repeated. The goal is to reduce the range of responses and attain something closer to expert consensus. The Delphi method has been widely adopted and is still used today.[148] The Delphi methodology offers advantages over other modes of consensus building (such as round table discussions)[149] because:

1. discussions are electronic/internet-based, making it easier for experts to participate impartially than during face-to-face discussions
2. anonymity is preserved, thereby allowing panellists to freely express their opinions without feeling pressure to agree with group members[55, 150, 151]
3. questionnaires are implemented over a period of at least six weeks, thereby providing panellists time to carefully consider discussion topics.[149]

The Delphi methodology has previously been used in health-related studies to better understand the varied symptom presentation in patients who are at different stages of their disease trajectory.[152]

3.6.2 Materials

3.6.2.1 Literature Review

The construction of the SATp was based on a review of CRC survivorship literature and subjected to a series of validations. The items focused on long-term issues experienced by patients offered treatment with curative intent (Stages I to III). The needs of those with Stage IV CRC are entirely different and in most cases are palliative;[143] thus, they were not included.

3.6.2.1.1 Item Generation

A systematic search was performed using PubMed/Medline, CINHAL and Cochrane Online Library Reviews/Trials databases from 1980 to 2014. Search terms were used either singularly or in combination in the index lists of the relevant databases. The search terms used were ‘lower bowel cancer’, ‘rectal cancer’, ‘colon cancer’, ‘effects of treatment’, ‘effects of adjuvant therapy’, ‘effects of surgery’, ‘follow-up care’, ‘survivorship care’, ‘quality of life’ and ‘patient unmet needs’. Free text words were used to supplement the medical subject heading search terms for Medline.

The search of literature focused on the long-term effects of CRC treatment and their prevalence. Titles and abstracts of 650 references were reviewed and 69 studies satisfied the following inclusion criteria (Figure 3.1):

- published in English
- reported empirical research
- reported epidemiology of CRC
- focused on developing a symptoms/needs-assessment questionnaire for patients post–cancer treatment—particularly CRC
- reported the side-effects of CRC treatment
- focused on patients’ QoL after CRC treatment.

From the 69 reviewed papers, 340 possible post–CRC treatment problems were extracted. Duplicates were removed, yielding 100 items. These items were assessed by a team of three clinicians (medical doctor, public health specialist and nurse). Unclear items and those with similar meanings were identified and discussed for relevance, which left issues considered common for CRC patients post-treatment. Thirty-two problems were grouped into three domains: psychological (n = 6), physical (n = 20) and social (n = 6) (Figure 3.2).[29]

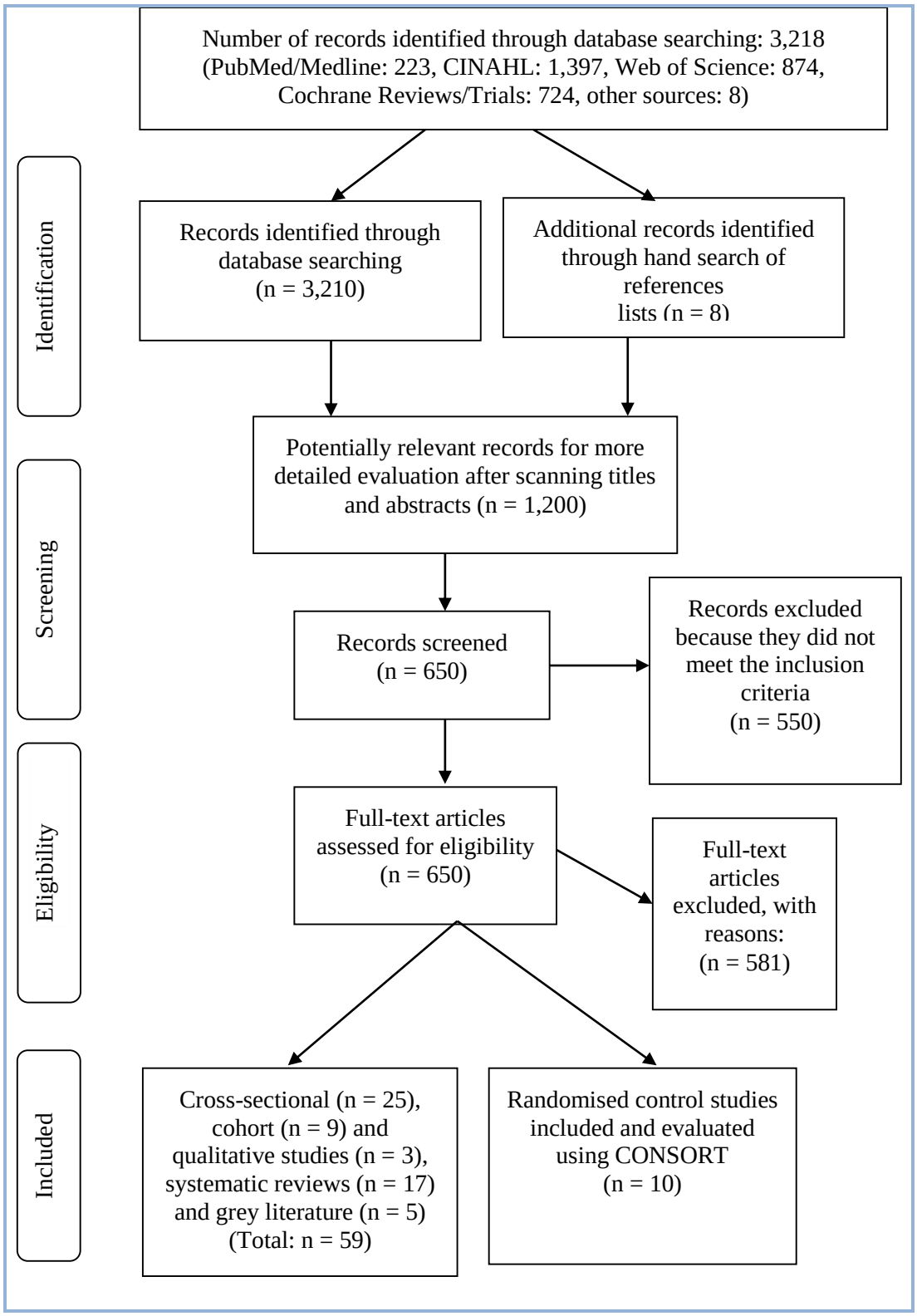


Figure 3.1: Flowchart of the Methods Used to Identify Evidence Relevant to Study 1

3.6.3 Item Reduction

The 32 identified items were further reduced by assessing them against published prevalence of CRC treatment side-effects. Any items that had a frequency of 5 or less per 100 were removed because this was deemed uncommon by the expert panel. The modelling was based on a typical cohort of 100 patients with CRC.

From the reviewed articles, the epidemiology of CRC suggested that approximately 70% of cases are located in the colon and 30% in the rectum.[153] In addition, 50% of patients with colon cancer are likely to be in Stages II or III at diagnosis,[72, 154] while rectal cancer cases are evenly spread across all stages.[72] For Stages I to III of CRC, nearly all patients (98%) undergo surgery,[72] while treatment with chemotherapy and radiotherapy depends on the location (colon or rectum) and stage. For colon cancer, the majority (75.5%) of Stage III patients receive chemotherapy,[97] while chemotherapy for patients at Stages I and II is less common because there is no general agreement on its use for these patients.[111] Approximately 19.6% of patients are offered chemotherapy during Stage I[155] and 20 to 24% during Stage II.[155] Radiotherapy has a limited role in the treatment of colon cancer; however, for rectal cancer patients, it may be offered at all stages: Stage I—19.6%,[155] Stage II—36%[155] and Stage III—57%.[97]

Further, the literature suggests that patients may have treatment side-effects or issues associated with treatment in the physical, psychological and social domains.[156, 157] The prevalence of the published side-effects under these domains are summarised in Figure 3.2. Most side-effects in the physical domain relate to bowel issues (7 to 20%),[1, 2, 4] urinary issues (31 to 38%)[1] and sexual dysfunction (26%).[6] The long-term psychological issues commonly reported are fear of recurrence (67 to 68%)[1, 8] and depression (25%).[7] For social problems, the greatest burden is financial difficulties (~50%),[22] followed by activity limitation (15%).[3] Based on these statistics, it is anticipated that, in a sample of 100 Stage I to III CRC patients (excluding 22.5% of Stage IV and 3–5% of un-staged CRC) with typical epidemiology as above, 53 will have colon cancer and 22 will have rectal cancer. Of these, 75 patients will receive surgery, 36 will be offered chemotherapy and 11 will be offered radiotherapy (see Appendix 3.1).

Further, using modelling to illustrate the frequency of treatment effects in the cohort of 100 CRC patients, five to 10 of them will have some form of bowel dysfunction. It is anticipated that about seven to nine patients with rectal cancer (a cohort of 23 patients) who have had surgery and radiotherapy will report urological dysfunction. From this cohort, four patients who received chemotherapy will experience some form of peripheral neuropathy, and at least one to six patients will experience nausea, vomiting and weight loss related to chronic radiation enteritis.[1] Six rectal cancer patients will experience some form of sexual dysfunction.

The extent of psychological and social factors experienced by the entire cohort (colon and rectal) will be high. Nearly 50 patients will suffer some form of psychosocial problem—for example, about 50 patients will have fear of recurrence (details of the cohort modelling are shown in Appendix 3.1). Based on the modelling, items with fewer than five patients in the cohort were removed from the list; thus, two items (fractures and dysuria) were excluded. The results of the cohort modelling identified 26 items that were subsequently used to formulate the initial SATp questions, which were further subjected to a series of validation and testing.

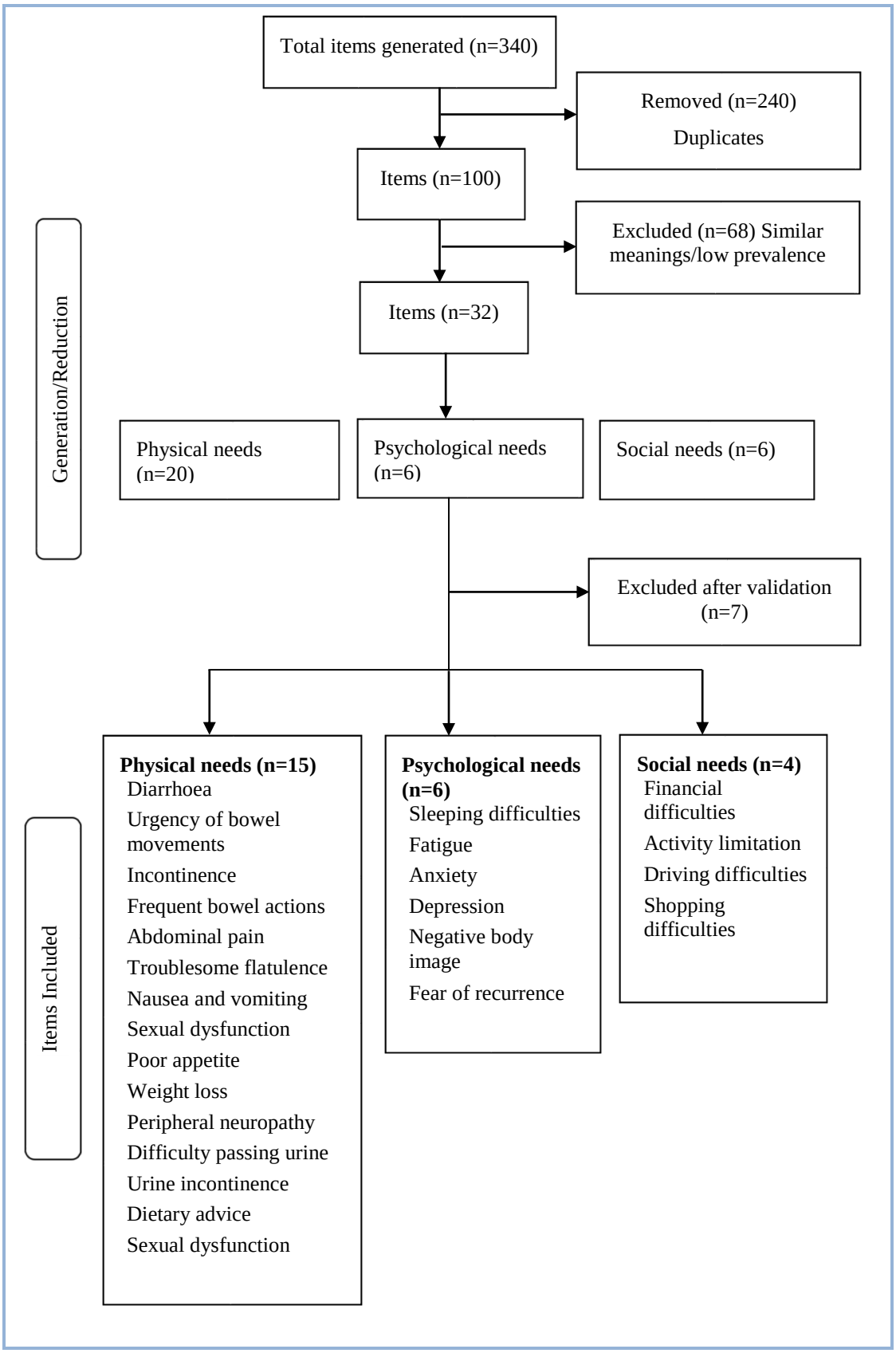


Figure 3.2: Process of Item Generation, Reduction and Validation for Development of the SATp

3.6.4 Content Validity of the SATp

The content was tested using a Delphi method. Initially, a group of health professionals involved in the follow-up care of CRC were identified and approached. As informed by the literature, questions of the problems experienced by CRC patients were formulated and sent to the panel of experts for suggestions and validation. These experts were also asked to list other problems CRC patients may present during the follow-up appointments.

3.6.4.1 Delphi Method

The primary researcher coordinated the responses of the panel of experts, who were selected based on their areas of expertise (seven health professionals—a GP, medical oncologist, radiation oncologist, CRC surgeon, CRC nurse specialist, dietician, psychologist, occupation therapist and social worker) or were patients who had completed treatment for CRC (10 patients). The researcher sent out the draft tool containing a list of CRC problems to the consenting experts via email, for them to provide their level of agreement of each item using a Likert scale on a questionnaire developed for this purpose. Details of this questionnaire are provided in Appendix 3.2. The panellists were asked to give a reason for each of their scores. Clear instructions were provided, with the expectation that there was to be a two-week turnaround for each round of the Delphi. Panellist responses were collated and an average score assigned to each item on the second round of the questionnaire to be re-sent to the panellists. The panellists were provided with a list of all panellists' de-identified comments. This process was repeated twice until consensus of at least 70% was reached for each item. The development and examination of this tool (SATp) by a group of experts ensured this tool's reliability and validity.

The 26 questions were rated on a Likert scale by the panel of health professionals and patients, and 90% had total scores > 3 out of a maximum score of five. Scores ≥ 3 were regarded by the panel as indicating high relevance. One physical item (constipation) and one social need (information need) with scores of two were removed from the list. Four other questions were combined into two because they tested the same issue (sexual dysfunction for males and females, and frequent bowel movements during

night and day). An additional two items suggested by the panel (dietary advice and troublesome flatulence) were added to the list. In total, 25 questions were included in the SATp questionnaire (Appendix 3.4).

3.6.5 Readability

The SATp was subjected to readability tests, such as the Gunning Frequency of Gobbledygook Index, Flesch–Kincaid Grade Level, Simple Measure of Gobbledygook (SMOG) Formula, and Flesch Reading Ease (FRE) Scales for functions of the number of characters, syllables, words and sentences in a text sample (these tests have been used extensively to measure the readability of health information).[158] This ensured that the tool could easily be understood by the general population of Australia (reading level Year 10, high school). A grade of 4.4 reading level was attained (acceptable range are grades four to six) and reading ease was 82.5% (maximum reading ease is 100%, with the higher the number, the easier it is for participants to read). On average, the SATp takes approximately five minutes to complete.

3.7 Data Analysis

Statistical analysis of SATp was conducted using the Statistical Package for Social Sciences (SPSS) Version 19.[159] The kappa coefficient was used to examine test–retest reliability at the item level, while Cronbach's alpha was computed to assess internal consistency. The Delphi results of the panellist score were computed and average scores calculated. Items with an average score of < 3 out of five for healthcare workers and patients were excluded from the list. Descriptive statistics were used to summarise the patients' demographics, clinical characteristics and needs identified by the SATp.

3.8 Study Identification of Participants for the Pilot Study

Participants for the pilot study were recruited from an outpatient cancer centre of SCGH—a tertiary referral teaching hospital located in Perth, Western Australia. Participants were identified from the outpatient electronic medical register, i.Clinical Manager (iCM iSOFT) Version 10,[160] which is commonly used at the SCGH. The

ICD-10-AM third edition diagnosis codes relevant to CRC (C18, C19, C20 and C21)[161] were used to retrieve all patients with CRC from the outpatient register. A sub-criterion was then employed to narrow the results down to patients who had active appointments at the time of identification (patients who still had scheduled follow-up appointments). Further eligibility criteria and exclusion criteria are shown in Table 3.1.

Table 3.1: Eligibility Criteria for Identifying Possible Study Participants from the Electronic Medical Records

Eligible Patients • 18 years or over • Active CRC follow-up at the SCGH outpatient clinic • Diagnosis of primary CRC (ICD-10 AM C18-C20) • ACPS, A-C • Treated for colorectal surgical intervention with curative intent (ICD-10 procedures 913, 915, 917, 918, 926, 927, 932, 933, 934, 935 and/or other organs if patient had a synchronous or secondary malignancy)
Ineligible Patients • Recurrent disease • Sole non-surgical investigations and procedures, such as colonoscopies, biopsies, insertion of catheters and drainage of abscess, hematoma or cysts

The researcher telephoned the potential participants identified from the clinic database, introduced them to the study, and invited them to participate. Those who verbally consented received an information sheet and consent form. The study was approved by the human research ethics committees from the participating hospital and university (QI3041 and HR 42/2012, respectively). Details of the consent form and participant information sheet are presented in Appendix 3.3.

3.9 Piloting and Pre-testing

Piloting of the draft SATp (developed through the Delphi method) was undertaken to assess its usefulness in identifying CRC-related problems. Patients involved in the Delphi study were excluded from the pilot/pre-testing of the questionnaire to prevent contamination. A group of 30 consenting patients agreed to pilot and pre-test the SATp. For participants who also consented to participate in Studies 2 and 3 of this project, their pilot results were treated as a baseline findings for these studies, and no further details were requested from these patients at baseline.

Test–retest reliability was assessed by administering the SATp to a subset of participants who agreed to fill it out on two occasions, approximately two weeks apart. The SATp was sent to 30 participants and then re-sent 14 days later. The kappa statistic (κ) was calculated to assess the test–retest reliability of the instrument. Kappa can range between one (perfect agreement) to slightly less than zero (no agreement). A κ value of > 0.80 is considered to reflect almost perfect agreement, while 0.61 to 0.80 indicate substantial agreement, 0.41 to 0.60 indicate moderate agreement, and 0.21 to 0.40 indicate fair agreement.[162] The question-by-question comparison showed substantial agreement with kappa in the range of 0.689 to 1.000 for all questions.

The 25-item SATp achieved moderate to high internal consistency, as demonstrated by the Cronbach's alpha coefficients for the three domains (psychological, social and physical) ranging from 0.706 to 0.903. The item-to-total score correlation coefficients for all items exceeded 0.595. This showed that questions within each of the three domains were assessing different aspects of the same construct. The final set of questions in the SATp are shown in Appendix 3.4.

3.9.1 Needs Identified

Participants in Study 1 were 69.2 (SD 9.9) years old on average, and had been diagnosed with cancer 26.7 months earlier (range 6–92, median 28). Sixty-five per cent had colon cancer, 34.8% had rectal cancer and 81.8% had one or more coexisting chronic illness. Of the 30 participants who piloted the SATp, a total of 149 needs were

identified by SATp, with an average of 8.1 needs per patient (median 7; IQR [3–12.25]). Identified needs were in the physical (53, 36%), psychological (53, 36%) and social (48, 32%) domains. The most commonly reported physical needs were troublesome flatulence (79%) and fatigue (41%). Psychological needs included fear of recurrence (53%), insomnia (53%), sexual dysfunction (36%), anxiety (36%) and negative body image (23%). Social needs included dietary advice (41%) and housework difficulties (45%).

3.10 Discussion

This study reports the development of a reliable and valid tool (SATp) to assist doctors and patients to identify symptoms or problems that may result from CRC treatment. The SATp satisfies the prerequisites for assessing the long-term needs of CRC survivors because it measures multiple dimensions of CRC-related needs. The items included in the SATp were developed via a rigorous literature review and by modelling the items using a simulated cohort of CRC patients to derive the most common symptoms experienced by this group. Further, the instrument integrates the experience of patients in follow-up care with expert input from health professionals involved in the care of CRC patients.

The preliminary results indicate that the SATp fulfils the current methodological standards for acceptability, internal consistency, and usability. Through an internal consistency process, it was possible to demonstrate evidence for a strong, structurally reliable SATp with Cronbach's alpha coefficients exceeding 0.7 in all three domains. The test–retest reliability also showed a level of agreement that was not due to chance, as evidenced by a kappa of 0.689 to 1.000.

Despite being at least six months post-treatment, each patient was experiencing a median of seven unmet needs, all in the three domains (physical, psychological and social). These domains have been reported by previous research, suggesting that these issues are important aspects for long-term survivors of CRC.[146] The initial results confirm that the tool can be self-administered. By examining the needs rated 'yes', the survey could potentially be used to alert practitioners to refer these patients to

secondary care or other appropriate allied health support services. For the SATp to be useful, regular use in general practice is required. It is yet to be demonstrated whether the SATp facilitates proactive management of related problems in general practice, and how GPs might address some of the problems identified, such as fear of recurrence. This will be addressed in Study 3 in Chapter 5.

The SATp was unable to test directly for concurrent validity and predictive validity. In primary care, there was no Gold Standard identified by literature that SATp would be tested against. SATp also failed to test these forms of validity due to the nature of the intended outcome. The SATp was to identify CRC related problems and act as a prompt sheet to guide a GP consultation, rather than a self-administered diagnostic tool. The expected responses were binary in nature (Yes/No) and with a clear intention of prompting further examination by the doctor. This examination by the doctor has been documented in Chapter 5 of the Thesis.

Despite these limitations, the research outlines some of the practical and operational benefits of a specific instrument for CRC patients attending general practice. Further, the practicality of the self-administration of this measure obviates the need for follow-up telephone interviews from health professionals. Thus, the SATp increases the practical feasibility and acceptability of assessing patient needs on an ongoing basis as a routine part of care. The application of the SATp in general practice may potentially yield a valuable pool of data on patient needs.

Chapter 4: Predicting Study Participants' Intentions to Attend a GP Following CRC Treatment (Study 2)

The study detailed in this chapter has been published in the *American Journal of Health Behavior*:

Ngune I, Jiwa M, McManus A, Hodder R. Predicting general practice attendance for follow-up cancer care. American Journal of Health Behaviour. 2015; 39(2):167-174. doi:http://dx.doi.org/10.5993/AJHB.39.2.2.

Permission to reproduce this work for education purposes has been granted (see Appendix 4.1)

This chapter presents the study examining participants' intentions to seek CRC-related health advice from a GP. It details the factors that may influence patients' decisions to seek health advice. This chapter presents the study design, theoretical framework guiding the formulation of the study, methodology and results.

4.1 Study Summary

Objective: This study examined the role of the Theory of Planned Behaviour (TPB) in influencing patients' intentions to seek health advice from a GP.

Methods: A questionnaire was developed based on the TPB to assess CRC patients' intentions to attend follow-up visits with a GP following CRC treatment.

Results: TPB factors accounted for 43.3% of the variance on future follow-up visits. Attitude alone explained 23.3% of the variance. Attitude and the presence of comorbidities significantly affected future intention to visit a GP (attitude: $R^2 = 0.233$, $F [1, 65] = 4.345$, $p < 0.01$; comorbidity: $R^2 = 0.128$, $F [1, 65] = 3.019$, $p < 0.05$).

Conclusion: Patients who believed their GP had the skills and knowledge to detect a recurrence and patients with comorbidities were more likely to visit their GP following CRC treatment.

4.2 Summary Statement

4.2.1 What is Known About the Topic

Previous studies have indicated that:

- there have been difficulties in implementing follow-up care for CRC patients in general practice[163]
- there is limited empirical evidence regarding the factors that influence uptake of follow-up care by patients in general practice
- the factors that influence patients' decisions to seek health advice from a GP about CRC-related problems have not been fully determined.

4.2.2 What this Study Contributes

This study is significant because it contributes the following elements to the literature on CRC care. It contributes:

- a key component of innovation involving the follow-up care of cancer patients in primary care, which includes increasing patients' confidence in the skills and knowledge of their GP regarding the current treatment of cancer
- the finding that it may be more effective to share the follow-up care of CRC patients who already attend their GP for other reasons, such as those with existing chronic illnesses.

4.3 Background

In Australia, an estimated 105,000 people are CRC survivors, and this number is expected to increase by 309 every year.[14] It is likely that the specialist care of patients with CRC will need to be reorganised due to the increasing number of survivors.[31] Patients who have been treated successfully may benefit from long-term support by a GP in addition to specialist care. In Australia, approaches such as GP-led cancer care

and shared care for managing patients with breast, colorectal and prostate cancers in general practice have been trialled.[35, 41, 49, 164-167] However, to date, conclusive evaluations nor have they been conducted on the effectiveness of these approaches, nor they have been widely adopted.[38, 122] For breast cancer and other GP-led models of cancer care trialled in Australia and the United Kingdom,[168] uptake has been slow.[169]

There has been detailed analysis of healthcare system factors that affect the implementation of GP-led model, such as: the flow of information from hospitals to general practice and vice versa; the training of GPs; and the associated costs.[167] However, limited attention has been given to identifying patient factors. Recent efforts to report patients' preferences for cancer care have indicated that a GP-led approach in managing cancer care is favourable.[35] However, exploration of these preferences has only been in the context of perceived satisfaction with the treatment provided.[36] More empirical evidence is required on other factors to be considered for patients to attend seek health advice from a GP.

CRC patients are generally older (median age 69 years) compared to other cancer patients, and 30 to 60% of those aged 70 years or older with CRC have concomitant health conditions.[170] To date, no studies have explored the role of concomitant health conditions in influencing patients' attention to seek health advice from a GP about CRC-related problems. Studies have reported patient factors that affect access to healthcare, such as ease of travel, area of residence (rural versus urban), cost of services, and ease of obtaining an appointment as determinants for attending a GP for cancer care.[41, 137] While patient factors are central to determining the uptake of programs, the factors affecting people's choices must also be determined. These determinants need to be explored within a behavioural framework that incorporates people's intentions, attitudes, perceived control and barriers, and influences felt from other people regarding health-seeking behaviours.[171]

Social and psychological models have an important role in increasing understanding of the factors that underlie health-related decisions and behaviours.[172] Many models have been applied to predicting the attendance of health programs among cancer patients, including the Health Belief Model,[173] Protection Motivation Theory,[174]

Health Locus Control[175] and Self-efficacy Theory.[176] However, the TPB has attracted growing interest in recent years and continues to dominate behaviour research.[172]

The TPB suggests that intention immediately precedes behaviour because it reflects a person's level of motivation and desire to perform a certain action.[172] Intention is determined by attitude, subjective norms and perceived behaviour control constructs.[177] Perceived behavioural control (PBC) is the perceived opportunities and resources available for performing a behaviour, and may directly lead to the behaviour if it accurately reflects actual control. Attitude is viewed as the perceived advantages and disadvantages of performing the behaviour. Subjective norms are the perceived social pressures (such as important people) that influence an individual to perform a behaviour or not.[62] A diagrammatic representation of this model is shown in Figure 4.1.

Among cancer patients, all three factors (attitude, subjective norms and perceived behaviour control) have been used to predict behaviours, such as adherence to exercise[178] and attendance and re-attendance at screening programmes.[57] Studies conducted by Courneya et al. that used the TPB to understand intention and behaviour after CRC diagnosis[178, 179] demonstrated that intention is the strongest determinant of future behaviour. However, little is known about the role of intention, personal attitude, PBC and subjective norms in CRC patients attending follow-up care with a GP, and the influence of comorbidities on these factors. The present study seeks to explore the role of comorbidities within the TPB framework in predicting intention and behaviour in CRC patients who have never attended follow-up cancer care in general practice.

The hypothesis of this study was that personal attitude, PBC and subjective norms would be independently associated with intention to seek health advice from a GP about CRC-related problems. In addition, the presence of comorbidities would influence this association.

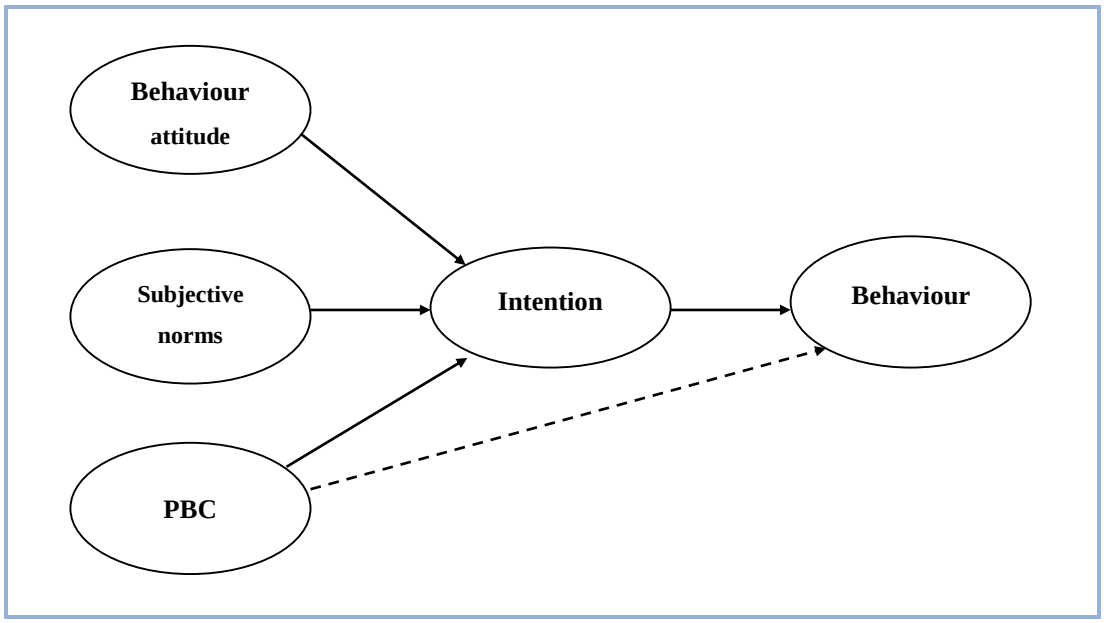


Figure 4.1: The TPB- Adapted from Francis JJ et al 2004[62]

4.3.1 Objectives

The main aim of Study 2 was to assess the factors that influence CRC patients' decisions to seek health advice from a GP.

4.3.1.1 Sub-objectives

The sub-objectives were as follows:

- to assess the influence of TPB constructs (attitude, subjective norms and perceived control factors) on patients' decisions to seek health advice from a GP
- to explore the role of clinical and respondent characteristics on the TPB constructs.

4.4 Methods

4.4.1 Study Design and Identification of Participants

A cross-sectional study design was used to predict patients' intentions to seek health advice from a GP about their CRC-related problems. The participants were identified through a process similar to Study 1, and invited to complete a questionnaire developed based on the TPB.

4.4.2 Eligibility

Participants for Study 2 were recruited from an outpatient cancer centre at SCGH—a tertiary referral teaching hospital located in Perth, Western Australia. Participants aged 18 years or older who had completed CRC treatment (surgery only or surgery and adjuvant therapy) and were still undergoing active follow-up at the outpatient cancer clinic in SCGH were eligible to participate in this study.

A process similar to that undertaken for Study 1 was followed to identify participants for this study. Participants were identified from the outpatient electronic medical register, i.Clinical Manager (iCM iSOFT*)* Version 10,[160] which is commonly used at the SCGH. The ICD-10-AM third edition diagnosis codes relevant to CRC (C18, C19, C20 and C21)[161] were used to retrieve all patients with CRC from the outpatient register. A sub-criterion was then employed to narrow the results down to only patients who had active appointments at the time of identification (patients who still had scheduled follow-up appointments). Further eligibility criteria and exclusion criteria are shown in Table 4.1.

Table 4.1: Eligibility Criteria for Identifying Possible Study Participants from the Electronic Medical Records

Eligible Patients • 18 years or over • Active CRC follow-up at the SCGH outpatient clinic • Diagnosis of primary CRC (ICD-10 AM C18-C20) • ACPS, A-C • Treated for colorectal surgical intervention with curative intent (ICD-10 procedures 913, 915, 917, 918, 926, 927, 932, 933, 934, 935 and/or other organs if patient had a synchronous or secondary malignancy)
Ineligible Patients • Recurrent disease • Sole non-surgical investigations and procedures, such as colonoscopies, biopsies, insertion of catheters and drainage of abscess, hematoma or cysts

The primary researcher telephoned the potential participants identified from the clinic database, introduced them to the study, and invited them to participate. The participants who verbally consented received a study information sheet and consent form that contained the study details. A protocol of reminder telephone calls and letters was followed to enhance participant compliance in the study. The relevant human research ethics committees from the hospital (QI3041) and university (HR 42/2012) approved the study.

4.4.3 Measures

Validated questions for assessing CRC patients' intentions to attend a GP were identified from the literature. Patients responded to questions adapted from a manual on constructing questionnaires based on the TPB.[62] Although the individual questions had been validated, they were still piloted by a group of five patients to assess for readability in an Australian context. Assessment of the internal consistency of the various items under each TPB constructs, as well as scoring of these items, were completed as outlined by Francis et al. (2004).

4.4.3.1 Demographic and Disease Information

The demographic characteristics included age, marital status, education, previous GP visits, employment status, location of cancer, type of treatment offered and existing comorbidities. The clinical characteristics were formulated based on patient-assessment questions identified in the Australian guidelines for cancer follow-up.[37] Table 4.3 presents the demographics and clinical characteristics of the participants from study 2.

4.4.3.2 Intention to Engage with a GP or a Specialist in the Future

The participants responded to questions adapted from a manual on constructing questionnaires based on the TPB.[62] Three questions that assessed this intention were: 'In the next six months, I am likely to attend a GP visit'; 'I'm likely discuss CRC related problems with a GP' and 'I'm likely to attend a specialist only for CRC-related problems'. The responses were coded on a Likert scale ranging from one (unlikely) to five (very likely) (see Table 4.2).

4.4.3.3 Personal Attitude about Seeking Health Advice from a GP for CRC-related Problems

Attitude was measured using questions requiring responses on five-point Likert scales, measuring responses from unlikely to likely, and strongly disagree to strongly agree. The three attitudinal items were: 'Attending a GP about my CRC: (i) is likely to detect problems and side-effects early, (ii) is likely to detect problems and side-effects early, or (iii) will reassure me'. Internal consistency for this three-item scale was 0.778 (Cronbach's alpha) (see Table 4.2).

4.4.3.4 Subjective Family and 'Important Others' Norms about Engaging with a GP

Subjective norms were measured by three items from Francis[62] on five-point Likert scales, which ranged from one (strongly disagree) to five (strongly agree). The three items were: 'Most people who are important—my family, specialist and cancer nurse—think I should attend a GP about my CRC'. Internal consistency for this three-item scale was 0.879 (see Table 4.2).

4.4.3.5 Perceived Behaviour Control Factors and Barriers Influencing GP Visits for CRC-related Problems

PBC factors were measured using four items from Francis,[62] also requiring responses on five-point Likert scales. Two items used adjectives on a five-point scale, which ranged from one (extremely easy) to five (extremely difficult), and one (strongly agree) to five (strongly disagree). One item tested the control factors and the other tested barriers. The control items were: 'Making a routine appointment with a GP is extremely difficult to extremely easy (1 to 5), and it is easy for me to attend a GP about my CRC—strongly agree to strongly disagree'. The internal consistency for this two-item scale was 0.803. The barrier factors were: 'It is affordable for me to attend a GP about my CRC (strongly agree to strongly disagree)' and 'for me to travel to see a GP about my CRC is extremely difficult to extremely easy'(1 to 5). The internal consistency for this two-item scale was 0.853.

4.4.4 Scoring and Statistical Analysis

A five-point Likert scale (described above) was used to score attitude, social norms and the perceived behaviour control items identified above. An overall score for each construct was calculated by taking an average score of the items under each construct. Negatively worded endpoints ('barriers') were reverse-scored prior to analysis, so that a high score indicated ease of attending a GP, while a low score indicated a reluctance to do so. Details of the scoring are provided in Appendix 4.2.

Table 4.2: TPB Questions

Factors Influencing Seeking Health Advice from a GP	Questions	Likert Scale	Internal Consistency
Intention to engage with a GP in the future	'In the next six months, I am likely to attend a GP visit.'	1 = unlikely 5 = very likely	N/A
Intention to discuss CRC related problems with a GP in the future	"In the next six months, I likely to discuss CRC related problems at with a GP	1 = unlikely 5 = very likely	N/A
Intention to engage a specialist only for CRC-related problems	'In the next six months, I am likely to attend a specialist only for CRC related problems.'	1 = unlikely 5 = very likely	N/A
Personal attitude	'Attending a GP about my CRC is likely to: (i) detect problems and side-effects early, (ii) detect problems and side-effects early or (iii) reassure me.'	1 = unlikely 5 = very likely	0.778 (Cronbach's alpha)
Subjective family and 'important others' norms	'Most people who are important—my family, specialist and cancer nurse—think I should attend a GP about my CRC.'	1 = strongly agree 5 = strongly disagree	0.879
PBC factors and barriers	Control items: 'Making a routine appointment with a GP is extremely difficult to extremely easy.' 'It is easy for me to attend a GP about my CRC (strongly agree to strongly disagree).'	1 = extremely easy 5 = extremely difficult 1 = strongly agree 5 = strongly disagree	0.803
	Barrier factors: 'It is affordable for me to attend a GP about my CRC (strongly agree to strongly disagree).' 'For me to travel to see a GP about my CRC is extremely difficult to extremely easy.'	1 = strongly agree 5 = strongly disagree 1 = extremely easy 5 = extremely difficult	0.853

4.5 Questionnaire Readability

The questionnaire was subjected to readability tests, such as Gunning Frequency of Gobbledygook Index, Flesch–Kincaid Grade Level, SMOG Formula, and FRE Scales for function of the number of characters, syllables, words and sentences in a text sample. These tests have been used extensively to measure the readability of health information.[180] The Flesch-Kincaid Grade Level and FRE Scale of a grade 4.4 reading level was attained (acceptable range are grades four to six), and reading ease was 82.5%. On average, the questionnaire took 10 minutes to complete.

4.6 Data Analysis

Descriptive statistics were computed using the SPSS Version 19[159] to summarise the participants' personal and clinical characteristics. Pearson's correlation coefficients were used to examine the strength of association between intention to visit a GP in the future and attitude, subjective norms and PBC. Multivariate analysis (with simultaneous entry) was conducted to examine individual and combined contributions of attitude, subjective norms and PBC on future intention to 'Intentions to attend a GP', 'Discuss CRC related problems with a GP', and 'Intentions to visit a specialist only'. Finally, squared semi-partial correlations were computed for each independent variable in the regressions to estimate the independent contribution of each variable to the model.[181]

In simultaneous model of regression analysis, all independent variables are entered simultaneously and on an equal footing into the model. [159] In this strategy, the analysis is dictated in advance by purpose and logic of previous research but does not replicate the analytic approach of the guiding studies. In this case, the independent variables are entered according to their statistical contribution in explaining the variance in the dependent variable. [99] Such a research strategy is most appropriate when no logical or theoretical basis for considering any independent variable to be prior to any other, either in terms of a hypothetical causal structure of the data or in terms of its relevance to the research goals. [159] In the hierarchical model, all variables are entered cumulatively according to some specified hierarchy and it replicates an analytic process of similar research. [159] Stepwise regression analysis on the other hand, the investigator has a

large pool of potential independent variables and there is very little theory to guide selection among them. [159]This may pose a problem as a relatively large number of independent variables is used. In stepwise regression analysis, significance test of an independent variable contribution to effect size proceeds in ignorance of the large number of other such tests being performed at the same time for the other competing independent variables, meaning that the analysis capitalises on chance. [99, 207]

The hierarchical and stepwise regression analysis were considered unsuitable to this analysis since the independent variables - 'Intentions to attend a GP', 'Discuss CRC related problems with a GP', and 'Intentions to visit a specialist only' were considered equivalent before the analysis. Also, because of the nature of the scoring methods, the main outcome measures failed tests of Normality. A simultaneous regression analysis is robust to some departure from Normality. The number of participants recruited in this study was such that the distribution of the mean scores would be approximately Normal. Therefore, the planned correlations and regression models were considered appropriate. The analyses were likely to be conservative in the sense that standard deviations may be exaggerated, making any p-values for association higher than they would have been otherwise.

4.7 Results

4.7.1 Demographic and Clinical Characteristics

Sixty-six of the 88 participants recruited, returned the completed questionnaires. Participants were 69.2 (SD 9.9) years on average, with 30.4% single or widowed, and 71.2% retired. On average, the participants had been diagnosed with cancer 26.7 months earlier (range 6–92, median 28), while 81.8% had an existing chronic illness, 65.2% had colon cancer, 31.8% had rectal cancer, and 1.5% had both colon and rectal cancers (see Table 4.3).

Table 4.3: Participant Demographic and Clinical Characteristics*

Participant Characteristics (n = 66)		Number of Participants (%)
Gender	Male	26 (39.1)
	Female	40 (60.9)
Age	Mean (SD)	69.2 (9.9)
Age (years)	≤ 60	12 (12.0)
	61–70	23 (34.8)
	71–80	21 (31.8)
	≥ 81	10 (15.2)
Marital status	Never married	10 (15.2)
	Widowed	13 (19.7)
	Married	31 (48.5)
	Divorced/separated	10 (15.1)
	De facto partner	1 (1.6)
Education level	Completed primary school	7 (10.9)
	Year 10 or equivalent	29 (43.8)
	Year 12 or equivalent	4 (6.1)
	Trade certificate/TAFE	12 (18.2)
	University/College of Advanced Education	14 (21.2)
Employment	Self-employed	4 (6.3)
	Employed for wages, salary or payment in-kind	10 (10.6)
	Engaged in home duties	1 (1.5)
	Unable to work	2 (3.0)
	Unemployed	1 (1.5)
	Retired	47 (71.2)
	Other reasons	4 (6.1)
Cancer location	Colon	43 (65.2)
	Rectum	21 (31.8)
	Colon and rectum	1 (1.5)
Cancer stage	Stage I	17 (25.8)
	Stage II	30 (45.5)
	Stage III	19 (28.8)
Comorbidity	Yes	54 (81.8)
	No	12 (18.2)
Visited a GP	Yes	57 (86.4)
	No	9 (13.6)

* Clinical characteristics were formulated based on patient-assessment questions identified in the Australian guidelines for cancer follow-up.[182]

4.7.2 Association between Attitude, Subjective Norms, PBC and Intention to Visit a GP

Associations between the components of the TPB model were examined (see Table 4.4). Only personal attitude and subjective norms were positively correlated with future intention to visit a GP for health advice about CRC-related problems, with

correlations ranging from 0.43 to 0.59 (medium effects). These two constructs—personal attitude ($r = 0.585$, $p < 0.01$) and subjective norms ($r = 0.427$, $p < 0.05$)—were also positively correlated with intention to discuss CRC side-effects with a GP in the future. PBC was not correlated with intention to attend GP follow-up visits and discuss CRC side-effects with a GP.

Table 4.4: Correlations between the TPB and Intention to Attend Follow-up Visits with a GP

(n = 66)	**Attitude**	**Subjective Norms**	**Perceived Barriers**	**Perceived Control**
Intention to engage with a GP	0.585*(p = 0.000)	0.427*(p = 0.000)	0.116(p = 0.352)	0.239(p = 0.053)
Intention to discuss CRC related problems with a GP	0.478*(p = 0.000)	0.280**(p = 0.025)	0.112(p = 0.372)	0.119(p = 0.341)
Intention to attend a specialist only for CRC-related problems	0.358**(p = 0.003)	-0.176 (p = 0.165)	0.030 (p = 0.814)	-0.037(p = 0.771)
Attitude	-	0.696*(p = 0.000)	0.137(p = 0.272]	0.201(p = 0.105)
Subjective norms		-	0.164(p = 0.195)	0.283*(p = 0.024)
Perceived barriers	-	-	-	0.815*(p = 0.000)
Perceived control	-	-	-	-

* Correlation is significant at the 0.01 level (two-tailed). ** Correlation is significant at the 0.05 level (two-tailed).

4.7.3 Combined and Specific Contribution of Attitude, Subjective Norms and PBC

Table 4.5 shows how the TPB constructs—attitude, PBC and subjective norms—predict future intention to visit a GP to discuss CRC treatment side-effects. The results of the multivariate analysis supported the hypothesis that personal attitude would account for significant variance in future intention to attend GP follow-up visits ($R^2 = 0.233$, $F [1, 65] = 18.881$, $p < 0.01$) (see Table 4.5).

Table 4.5: Multivariate Analysis Using Attitude, Subjective Norms and PCB to Predict Future GP Attendance

(n = 66)	B	t	F-value	p-value	Effect Size	Variance R^2 Adjusted
Future intentions to engage with a GP						
Attitude	0.659	4.345	18.881	0.000	0.233*	
Subjective norms	0.220	0.895	1.242	0.219	0.016*	$R^2 = 0.433$
PBC	0.209	1.512	0.107	0.224	0.024*	
Comorbidity	0.781	3.955	9.113	0.004	0.128	

*

There was a strong effect size for the influence of all the four variables on future intention to attend a GP. These factors together accounted for 43.3% of the variance. For the unique contribution of the independent variables (attitude, subjective norms, PBC and perceived barriers), the analysis indicated that participants' attitude and presence of a comorbidity accounted for 23.3% and 12.8% of the variance in future intention to visit a GP for health advice about CRC-related problems respectively. (see Table 4.5).

When the social, demographic and clinical variables (age, gender, marital status, presence of comorbidity and cancer stage) were entered into the regression model, statistically significant associations emerged. Patients with a coexisting chronic illness had a more positive attitude towards engaging with general practice than did those who did not ($p < 0.01$). The effect of comorbidity was not seen in the other constructs (PBC and subjective norms). Comorbidity alone accounted for 12.8% of the overall variance. Comorbidity was also significantly associated with future intention to visit a GP for CRC follow-up ($R^2 = 0.128$, $F [1, 65] = 9.113$, $p < 0.01$). Neither of the other two variables (PBC and subjective norms) significantly affected the relationship between the TPB constructs and intention to attend a follow-up visit with a GP.

4.8 Discussion

This study sheds light on how attitude, subjective norms and PBC influence CRC patients' intentions to engage with a GP. Specifically, it has documented significant associations between attitude, the presence of a chronic illness, and future use of GP services for care. The regression analysis also suggested that the combined effect of these factors had a strong influence (43.3%) on future intentions to seek health advice from a GP about CRC-related problems. Attitude and the presence of a chronic illness were responsible for 23.3% and 12.8% of this variance, respectively.

Analysis of the regression models provided a different picture regarding the other TPB constructs. Although personal attitude was strongly associated with patients' intention to visit a GP, PBC and subjective norms did not account for significant variance on future use of general practice services for CRC care. This finding is in contrast to research among CRC patients attending physical exercise sessions, which suggested that PBC has a significant influence on intentions.[179] PBC factors such as affordability, travel and ease of booking an appointment with a GP had limited influence on patients' intentions. As the mean age of participants was 69.2 (SD 9.9) years, PBC may not have had as strong an influence on this age category in Australia due to government-subsidised GP consultations and travel concessions.

Other studies show that CRC patients living alone have a more positive attitude towards seeking health advice from a GP about their CRC-related problems than do people who are married or living with a sibling or friend.[183] However, this study found that socio-demographic characteristics, such as age and marital status, had no effect on patients' attitude towards visiting a GP for health advice. The only statistically significant association with socio-demographic and clinical characteristics was that patients with a coexisting chronic illness had a more positive attitude towards attending a GP for CRC-related health advice ($p < 0.05$). This may be expected as 30 to 60% of CRC survivors aged 70 years or older have a coexisting chronic illness[170] and are more likely to attend primary care for ongoing follow-up.

4.9 Conclusion

In summary, this study examined whether the TPB constructs influenced patients' intentions to attend follow-up visits with a GP post–CRC treatment. The results suggest that patients' attitude can predict intention to visit a GP, and patients with an existing chronic illness are more likely to attend a future follow-up visit with a GP. Socio-demographic variables, such as age, marital status and employment status, do not appear to have a significant influence.

This information is valuable because it informs interventions implemented for follow-up care in general practice. Educating patients about how GPs can help them with their CRC-related issues may increase their confidence in seeking medical advice for issues that continue to affect their QoL. In addition, by identifying patients with a coexisting chronic illness, it is possible to target those who would benefit from follow-up through general practice.

4.9.1 Clinical Implications

The findings of this study will inform intervention efforts aimed at supporting CRC survivors. Intervention efforts are likely to be most effective by tailoring programs to the needs of CRC patients during follow-up care in a general practice setting.

4.9.2 Limitations

The results of Study 2 should be interpreted with caution for the following reasons. These findings may only be applicable to comparable patients with CRC. Also, the intention to attend a GP visit may not necessary result in patients reporting CRC related problems with a doctor. The sample size was relatively small and homogenous in terms of age. Future research may benefit from a larger sample with younger participants. Additionally, PBC may influence the intention of younger participants, who may perceive greater barriers to attending consultations with a GP. The data from this study should be further validated by observing actual practice as predicted by the questionnaire.

Chapter 5: A trial of the Self-assessment Tool (SATp Intervention) (Study 3)

This chapter describes the trialling of the SATp developed in Chapter 3. It discusses the study design, the theoretical framework guiding the development of the study, the methodology and the findings.

5.1 Summary

Background: Patients treated for CRC experience considerable physical, social and psychological morbidity.

Methods: A total of 66 participants with localised (Stages I to III) CRC were enrolled in a prospective study. Following collection of baseline data, participants completed the SATp each month over a five-month period. They were encouraged to visit a GP with a copy of their SATp to assist in the management of any problems associated with their CRC treatment. The GPs' notes were reviewed for management actions over the five-month period.

Results: Of the 66 participants who completed the study, 86% visited a GP over the five-month study period. A total of 547 problems were identified (median 7; IQR [3–12.25]). Participants with physical problems were more likely to consult their GP ($p = 0.05$) than were those with social or psychological problems. This trend was demonstrated in participants with diarrhoea (OR 1.84, 95% CI 1.05–3.21, $p = 0.03$). The number of problems experienced by participants did not appear to have any influence on the decision to visit a GP. Self-reported psychological problems ($p < 0.01$) significantly reduced over the five-month period. There were no statistically significant reductions in the number of physical or social problems, but SATp helped identify these problems during GP consultations. GP consultations (n = 117) resulted in a total of 78 management actions. Of these, 25 of 78 (32%) were prescriptions, 17 of 78 (22%) were investigations and nine of 78 (11.5%) were referrals. Prescriptions

were mostly for antidepressants (nine of 25, 36%), sedatives (six of 25, 24%) and analgesics (three of 25, 12%).

Conclusion: This pilot study found that regular use of the SATp facilitates the identification of CRC treatment–related problems. Some of these problems could be addressed in primary care. The SATp should now be evaluated in a randomised control study to assess its effect in reducing CRC problems following treatment.

5.2 Background

Patients with CRC experience physical and psychological morbidity.[3] Treatment for CRC includes surgery and, in some cases, chemotherapy and/or radiotherapy. This may result in long-term physical problems, such as bowel dysfunction, urinary problems and neurological deficits.[1, 18] Psychological effects (such as anxiety,[7, 19] depression[7, 19] and fear of recurrence[1, 20, 21]) and social problems (such as financial difficulties[22] and activity limitation[1, 23]) may also affect patients for many years following treatment.

Interventions for CRC patients, such as telephone support, have been effective in addressing problems following treatment.[52] Support is usually provided to patients immediately after discharge from hospital. However, there is evidence that some treatment-related side-effects may present or worsen many months after treatment.[1] Other side-effects and problems may persist even longer than this.[1] Further, some treatment side-effects or problems such as sexual dysfunction, anxiety and depression may manifest some time after treatment.[1]

Most people with CRC are now living beyond five years post-treatment and have other comorbidities for which they regularly visit their GPs.[32] Between 30 and 60% of CRC survivors aged 70 years or older have at least one other health condition.[117] The overall five-year survival rate for people treated for CRC in Australia is 89%.[14] As the survival of patients with CRC improves, GPs may find that they occupy a larger proportion of their practices, and supporting these people may contribute a significant burden to GPs' workload.

In Australia, it is estimated that a GP encounters 200 cancer patients each year.[184] As GP services are the first point of contact in the Australian health system, there is potential for GPs to support cancer patients, despite ongoing specialist care. Moreover, there is evidence that cancer patients present to a GP with cancer-related side-effects or symptoms of recurrence, even when receiving ongoing management by their specialist.[35]

Thus far, only limited approaches to support CRC patients beyond the acute treatment phase have been trialled in general practice. The few studies that have trialled GP-led interventions focused on the organisation of patient care and flow of information between hospital and primary care.[123-125, 169] Although these studies make recommendations regarding communication between the GP and hospital, data on which patients' problems were addressed during visits with the GP are limited.

Therefore, the current study provided patients treated for CRC with a self-completed needs-assessment measure (SATp) to monitor their treatment-related side-effects. Participants were encouraged to take their completed SATp to any future GP visits. This intervention was offered alongside routine hospital follow-up visits. A pilot study was conducted to assess the feasibility and effect of the intervention on identifying the participants' problems associated with CRC treatment.

5.3 Primary Hypotheses

The main aim of Study 3 was to test whether the SATp developed in Study 1 would identify physical, psychological and social problems related to CRC treatment, and whether the problems identified by patients in the SATp would be addressed during GP consultations. The following hypotheses were tested:

1. whether the SATp intervention identified the physical, psychological and social problems of CRC patients following treatment
2. whether these physical, psychological and social problems were addressed when participants presented the SATp to their GP.

5.4 Methods

5.4.1 Study Design

A prospective pre-post study was undertaken in Western Australia with people at Stages I to III CRC. The basic premise behind the use of this design involves obtaining a pre-test measure of the outcome of interest prior to administering some treatment, followed by a post-test on the same measure after the intervention. Administering a test at baseline can determine whether the prerequisites have been met. [152] Also, knowledge of the group at the beginning provides guidance for future activities as well basis for comparison of the results. The advantage of this design is ability to show methodological rigour without use of a control.[152]

This design was adopted for ethical reasons. The intervention was considered beneficial to all patients on follow-up care for CRC in this study site and would have otherwise disadvantaged some patients if a control was introduced. Participants from Study 2 were invited to participate in the trial of the SATp. They completed a SATp (developed in Chapter 3, Study 1) monthly, and were asked to take the SATp with them whenever they consulted their GP. With participant's permission their GPs were surveyed concerning the issues they presented with, and were asked to describe how the problems were addressed.

5.4.2 Recruitment and Ethical Approval

The participants were selected from a convenience sample of patients (n = 250) attending an outpatient CRC clinic of a tertiary referral hospital in Perth, WA. Those aged 18 years or over who had completed CRC treatment with curative intent (Stages I to III) were invited to take part in Study 2. Patients with Stage IV CRC were excluded from the study because their problems were likely to be palliative.[185] In addition, treatment side-effects are most likely to persist beyond 12 months post-treatment.[1] Participants were excluded if they were unable to provide informed consent (see Figure 5.1).

The potential participants were telephoned by the primary researcher and invited to participate in the study. The participants who consented to take part received a study information sheet and consent form. The participants were asked to nominate their regular GP, who was then contacted and advised that the patient was participating in the study, and that the researcher had consent to access their records. The baseline demographic and clinical information of the study participants was ascertained. Data were collected from participants who declined to participate, but consented to provide demographic and clinical data from their hospital. The relevant human research ethics committees from the hospital (QI3041) and university (HR 42/2012) approved the study. Of the potential 88 participants, 66 completed the study.

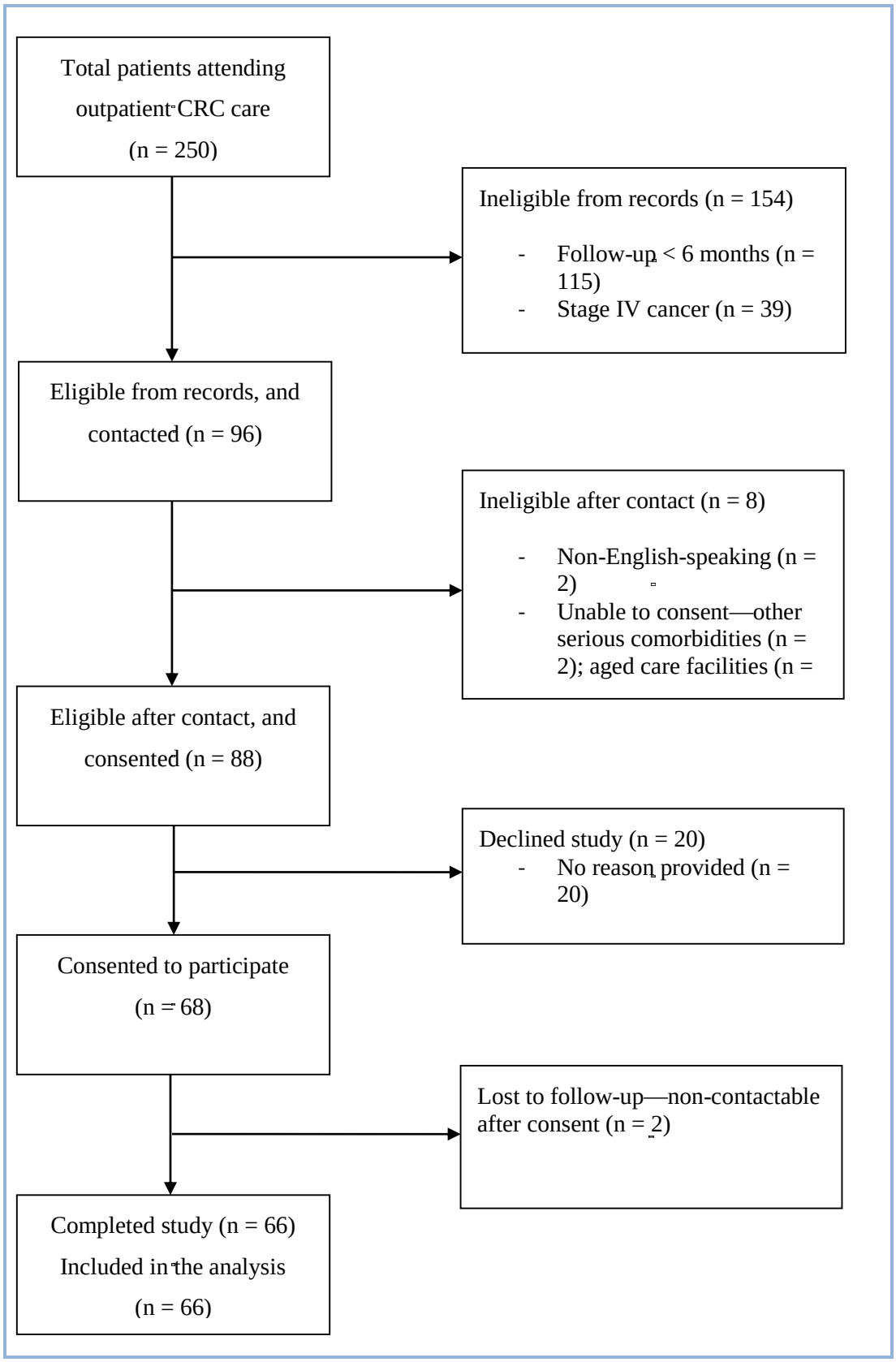


Figure 5.1: Study Flow Diagram

5.4.3 Principles Underpinning Trialling of the SATp

This study used the Glasziou and Haynes model of evidence-based medicine that outlines the path from research to improved health outcomes.[54] According to Glasziou and Haynes, there are substantial gaps between evidence and the management patients receive. To achieve better clinical outcomes for patients, clinicians must: (i) be aware of, (ii) agree with, (iii) adopt and (iv) act on evidence. The model further states that, even with high rates of compliance at each stage of the model, there may be little effect on patient outcomes. Hence, there must be strategies to assist GPs to progress through each stage of the model. To improve GPs' awareness of the CRC problems patients experience following treatment, participants of this study presented a CRC-specific validated problems checklist (SATp) to their GP. The SATp is a self-completed assessment tool to assist patients to identify problems post–CRC treatment, and then raise them with their GP.

Glasziou and Haynes further indicated that, even when clinicians know and accept the evidence, they often fail to action it. This is particularly the case for non-acute and preventive issues because they may not be the focus of a consultation. A simple reminder may be sufficient to prevent such omissions. This study incorporates a 'reminder' approach by using the SATp to aid consultation between CRC patients and their GPs. By participants presenting their SATp during a consultation, the GP becomes aware of CRC-related issues that may otherwise go unnoticed during a routine doctor–patient visit. Strategies such as using a pre-defined list of possible issues to prompt patients and/or their clinicians can improve communication and direct discussion during consultations.[186]

The intervention involved:

1. providing a booklet with copies of the SATp for participants to keep monthly records of problems they experience related to their CRC treatment
2. participants bringing problems identified to the attention of their GP during consultations using the SATp as a guide.

5.4.4 Development and Piloting of the SATp

The predetermined list of possible CRC related issues included in the SATp were identified from a review of the most common problems experienced by patients post–CRC treatment in published studies. The top 25 common problems were included on the draft SATp. The issues included in the SATp were then validated with two panels of patients and health professionals (via Delphi technique). The SATp was then pre-tested with a group of patients who satisfied the study's eligibility criteria. Detailed procedures for the development and validation of the SATp were described in Chapter 3 of this thesis—Study 1.[33]

5.4.5 Procedure and Measures

The intervention consisted of a baseline assessment followed by monthly follow-ups for five months. Participants may have had one or more consultations with a GP during the study period. The baseline assessment consisted of demographics, clinical characteristics and a baseline SATp. Demographic questions were derived from the Australian National Census Survey[187] and clinical characteristics included comorbidities, the cancer location, the pathological stage of the cancer, the type of surgery offered, the presence or absence of stoma, and whether neo-adjuvant therapy was offered. Follow-up consisted of questions about participants' physical, psychological and social problem related to their CRC treatment

5.4.6 Data Collection

The consenting participants were follow-up for five-month post baseline. They were provided a booklet of SATp questionnaires (developed in Study 1), which they completed at six time points (at baseline and monthly for five months). They were also invited to take their SATp booklet whenever they consulted their GP. At the start of the study, a baseline assessment of the patients' demographics and clinical characteristics, as well as the SATp, was completed. Thereafter, SATp was completed in triplicate carbon copies (participant's, researcher's and GP copies). Pre-paid envelopes were posted to the participants monthly so they could send back a copy of the completed SATp questionnaire. Posting of these envelopes was followed by a

courtesy telephone call five days later to confirm that the participants had received the envelope. A further telephone call was made two weeks later to participants whose SATp questionnaire had not been received by the researcher.

5.4.6.1 Outcome Measures

5.4.6.1.1 SATp Questionnaire

If participants made an appointment to visit their GP, they were encouraged to present their most recent SATp questionnaire. The primary outcome of the study was the number of problems experienced by each participant, while the secondary outcomes were the number of GP consultations and the management actions taken by the GPs during the visits.

The SATp recorded problems in three domains: physical, psychological and social. Management actions were categorised into referrals, prescriptions, investigations (laboratory and radiological tests) and health advice. CRC-related GP consultations were reported by the participants each month. The reliability of self-reported GP visits was ascertained from the GP notes at the end of the study. To assess the management actions taken by the GPs, they were sent a survey post-intervention to record whether any new prescriptions, tests or referrals were offered to participants during the study period. Details of these management actions were also collected by the researcher from the clinical notes at the end of the study (see below).

5.4.6.1.2 Review of Clinical Notes

A review of the clinical notes (integrated notes) was completed at the end of the study follow-up period (at five months). The researcher requested GPs to fax the clinical notes to a secure university fax line or (in cases where that was not possible) collected them personally. This was done to maintain patient confidentiality. The primary researcher independently reviewed the paper-based clinical records and abstracted data using a data collection form (see Appendix 5.1). Another trained researcher/GP reviewed the clinical notes and the primary researcher abstracted data in order to confirm the data. Any discrepancies noted were discussed with a third researcher who was also a GP, and consensus was achieved.

For each of the clinical records, the following information was recorded:

1. name of the patient
2. date of contact with the GP (whether at the practice or a home visit)
3. type of CRC-related management offered to the patient
    - referral for further management (to specialist or allied health worker)
    - investigations undertaken:
        - laboratory tests
        - radiological tests
    - prescription (type of medication offered)
4. CRC-related health advice offered.

Assessment of GP approaches to treating cancer-related side-effects using the domains of referral, investigation, prescription and health advice (used for the clinical data extraction form in this study) has been widely employed by other studies assessing the role of GPs in the follow-up of cancer patients.[48, 188-191] These domains (refer, investigate, prescribe and offer health advice) were also identified by the panellists in Study 4 (see chapter 6).

5.4.7 Sample Size

This study was conducted to determine whether the SATp helped participant to identify problems, and which participant-reported problems would result in GP management actions. This study also assessed the feasibility of the intervention (participant attendance to GPs visits, and acceptability of SATp). A sample size of approximately 60 participants gave 360 completed SATp records on which the analysis was based. This number was adequate to estimate the proportion of occasions on which at least one problem was identified for each participant, with reasonable precision (approximately ± 10%).[192] In total 66, participants were recruited for this study, allowing for a 10% attrition.[192]

A regression model was used to identify factors associated with GP actions in response to the problems. Presuming that each participant attends their GP twice (on average) during the five-month follow-up period, a sample of 60 people was adequate for the

regression model to identify independent variables showing a moderate effect size on the number of problems identified. The analysis took into account multiple CRC problems belonging to the same person (using a random effects regression model). As this was a pilot study, the data analyses provided information on the primary outcomes, as well as the correlations between observations from one month to another throughout the study.

5.4.8 Statistical Methods

5.4.8.1 Demographics and Clinical Characteristics

Descriptive statistics were computed using the SPSS Version 19 for Windows[159] to summarise participants' personal demographics and clinical characteristics. The characteristics of the participants who completed the study were compared with those who were invited to participate but declined the offer to assess any significant differences in their demographics.

5.4.8.2 SATp Assessment

The total number of problems identified by participants using the SATp in each domain (physical, psychological and social) for each time point (monthly) were calculated. The SATp recorded the presence or absence of common problems associated with CRC post treatment. The maximum number of problems recorded by a participant was 25 (the total number of problems identifiable using the SATp). A random effects regression model was used to identify factors associated with the scores (total and within domains) over time. This model took into account the correlation between responses from the same individual. The general estimating equation (GEE) model was used to identify factors associated with visiting the GP. Again, correlations within the data due to the multiple responses from each participant were taken into account in this model. This models was able to explicitly identify any trends over time in the outcome variables.

5.4.8.3 GP Visits: Intervention Adherence and General Practice Use

This study calculated the number of GP consultations for each participant where the SATp was presented. It also calculated the number of times each participant visited a GP and the proportion of participants who visited a GP for various problems.

5.4.8.4 Actions Taken by the GP

GP actions in response to SATp-identified problems were summarised, and relationships between these actions and the type of problems identified were analysed using the GEE model. A p-value of < 0.05 was considered significant in all tests.

5.5 Results

5.5.1 Participant Profile

Of the 250 CRC patients attending the target outpatient services, 88 were eligible for this study. Patients with Stage IV cancer (n = 39), patients unable to consent because they were hospitalised, non-English-speaking patients, patients in aged-care facilities (n = 8) and patients within six months of treatment (n = 115) were excluded. Of the 88 eligible participants, 66 consented and returned the completed questionnaires.

The average age of participants was 69.2 (SD 9.9) years, and had been diagnosed with cancer 26.7 months earlier on average (range 6–92, median 28). Of the participants, 65.2% (n = 41) had colon cancer, 34.8% (n = 23) had rectal cancer and 81.8% (n = 54) had one or more coexisting chronic illnesses. The characteristics of the study participants are provided in Table 5.1. The characteristics of the participants who declined to participate in the study were comparable, with the exception that males were significantly less likely to participate ($\chi^2 = 5.779$, df = 1, p = 0.02). Completion of the SATp at each scheduled time point was high, with a range of 98% at baseline and 100% throughout the study period. At baseline, two participants were lost to follow-up.

Table 5.1: Participants' Demographic and Clinical Characteristics*

Participant Characteristics (n = 66)		Number of Participants (%)
Gender	Male	26 (39.1)
	Female	40 (60.9)
Age	Mean (SD)	69.2 (9.9)
Age (years)	≤ 60	12 (12)
	61–70	23 (34.8)
	71–80	21 (31.8)
	≥ 81	10 (15.2)
Marital status	Never married	10 (15.2)
	Widowed	13 (19.7)
	Married	31 (48.5)
	Divorced/separated	10 (15.1)
	De facto partner	1 (1.6)
Education level	Completed primary school	7 (10.9)
	Year 10 or equivalent	29 (43.8)
	Year 12 or equivalent	4 (6.1)
	Trade certificate/TAFE	12 (18.2)
	University/college	14 (21.2)
Employment	Self-employed	4 (6.3)
	Employed for wages	10 (10.6)
	Engaged in home duties	1 (1.5)
	Unable to work	2 (3.0)
	Unemployed	1 (1.5)
	Retired	47 (71.2)
	Other reasons	4 (6.1)
Cancer location	Colon	43 (65.2)
	Rectum	23 (34.8)
Cancer stage	Stage I	17 (25.8)
	Stage II	30 (45.5)
	Stage III	19 (28.8)
Comorbidity	Yes	54 (81.8)
	No	12 (18.2)
Visited a GP	Yes	57 (86.4)
	No	9 (13.6)

* Clinical characteristics were formulated based on patient-assessment questions identified in the Australian guidelines for cancer follow-up.[182]

5.5.2 Intervention Adherence and General Practice Service Use

All participants completed the SATp each month during the five-month study period. In total, 88% (n = 57) attended a GP visit at least twice during the study. A higher number of GP–participant contacts were recorded in the second (33 of 66, 50.0%) and third (35 of 66, 53.0%) months, than in subsequent months (15 of 66, 22.7%). The number of participants who visited a GP during the five month follow-up period

decreased over the study period, with a significant reduction observed at four and five months (n = 15 of 66, p = 0.002 and n = 11 of 66, p = 0.001, respectively) (see Table 5.2).

Participants with physical problems visited their GP more often (p = 0.05) than those with social or psychological problems. In particular, participants who reported diarrhoea were significantly more likely to visit their GP than those without this symptom (OR 1.84, CI 1.05–3.21, p = 0.03) (see Table 5.2). The number of problems experienced by participants did not have any influence on their attendance to a GP.

Table 5.2: Results of a Regression Model in which the Dependent Variable is the Patient Attending Their GP

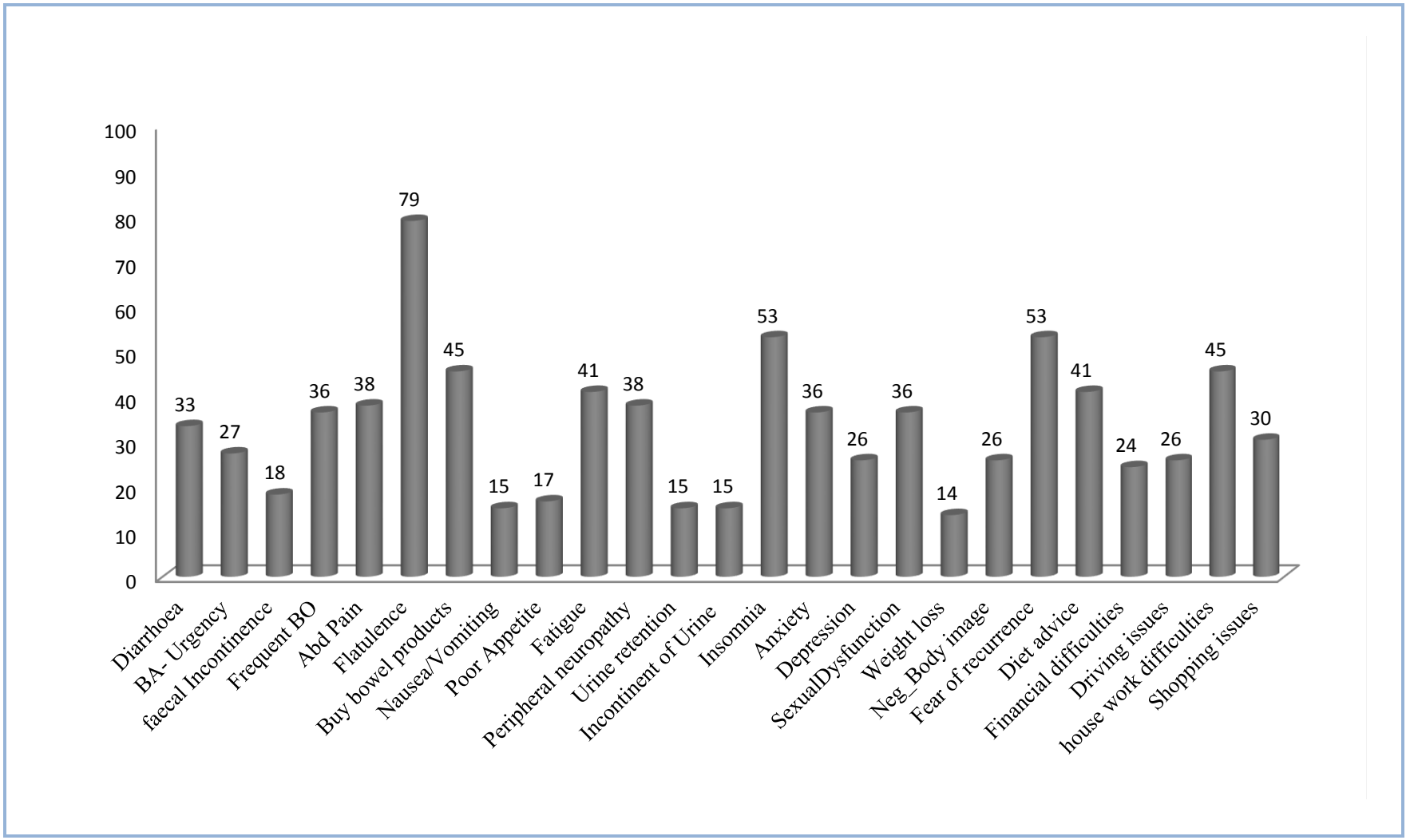
Variable	Number (%) Who Attended a GP	OR	95% CI for OR	p-value
Month 1	33/66 (50.0%)	1 (reference)		
Month 2	23/66 (34.9%)	0.52	0.26 to 1.05	0.0701
Month 3	35/66 (53.0%)	1.12	0.56 to 2.26	0.7498
Month 4	15/66 (22.7%)	0.29	0.13 to 0.65	0.0028
Month 5	11/66 (16.7%)	0.20	0.10 to 0.39	< 0.0001
Q1_Diarrhoea				
No	76/238 (31.9%)	1 (reference)		
Yes	41/92 (44.6%)	1.84	1.05 to 3.21	0.0329

1 Endpoint: Study participant went to a GP during the month. The symptom was reported at the commencement of the month (prior to the possible GP visit).

5.5.3 Identified Problems

Fifty-eight participants who completed the SATp and also visited a GP reported at least one problem related to treatment, with 96% of these participants reporting more than one such problem (range 3-12 problems). Over the 396 observations (66 participants over five observations), a total of 547 problems were identified on the SATp, with an average of 8.1 problems per participant (median 7, IQR [3–12.25]). Problems were in the physical (175, 32%), psychological (175, 32%) and social (197, 36%) domains. The most commonly reported physical problems were troublesome flatulence (79%, n = 52 of 66), need for dietary advice (41%, n = 27 of 66) and fatigue (41%, n = 27 of 66). Psychological problems included fear of recurrence (53%, n = 38 of 66), insomnia (53%, n = 38 of 66), sexual dysfunction (36%, n = 24 of 66), anxiety

(36%, n = 24 of 66) and negative body image (23%, n = 15 of 66). Social problems included housework difficulties (45%, n = 30 of 66) (see Figure 5.2).



Key: BA = bowel action; Abd = abdominal; Neg = negative

Figure 5.2: Percentage of Participants with Each Issue as Identified by the SATp (n = 66)

A high proportion of participants who reported a physical or psychological problem were in Stage II (93.3 and 86.7%, respectively) and Stage III (94.7 and 86.2%, respectively) compared to Stage I (76.1 and 70.1%, respectively). However, this difference was not statistically significant (Table 5.3). There was a gender difference with respect to the type of problem reported by participants, with men reporting more social problems ($p = 0.03$) than women. The SATp scores varied across domains over time, with a major decrease evident in the second month for the psychological domain. Physical and social problems remained similar throughout the study period. This trend is shown in Figure 5.3. The greatest improvement was observed in psychological problems, with a statistically significant reduction in the number of problems reported by participants in all time periods ($p < 0.01$) compared to the baseline (Table 5.4).

Figure 5.3: Proportion of Participants Reporting the Various Types of Problems

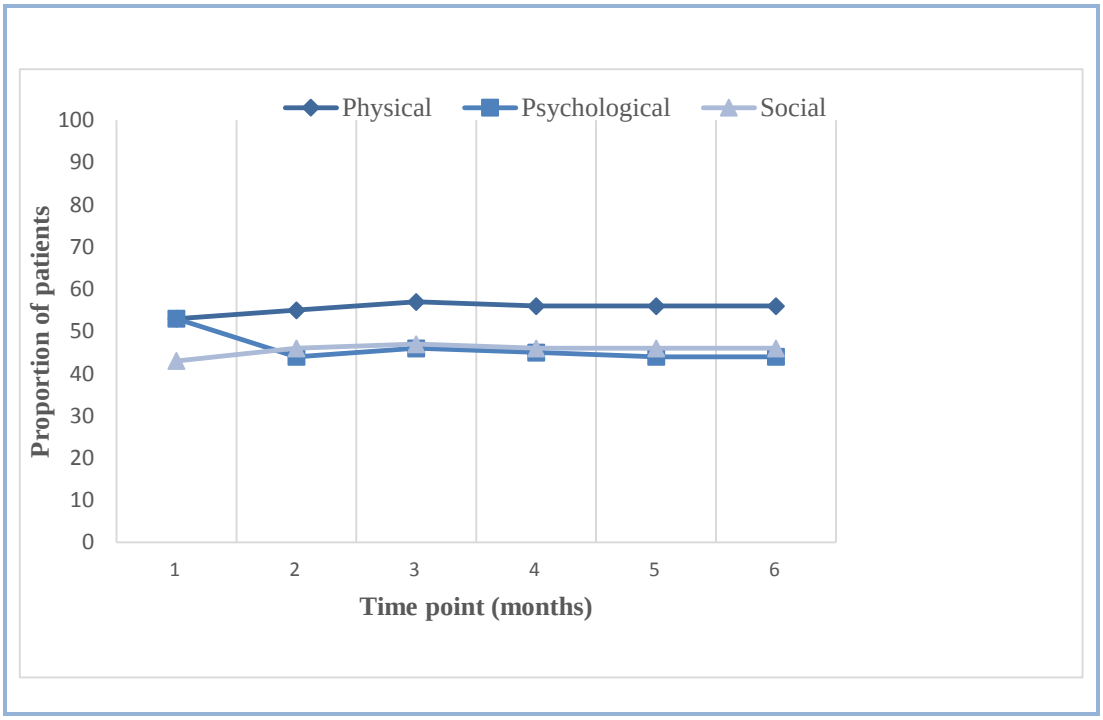


Table 5.3: Comparison of Symptoms or Problems by Gender, Cancer Location and Cancer Stage

		Gender (n = 66)			Cancer Location (n = 66)			Cancer Stage (n = 66)			
Problem	**Response**	**Male**	**Female**	***p*-value***	**Colon**	**Rectum**	***p*-value***	**Stage I**	**Stage II**	**Stage III**	***p*-value***
Physical (%)	Yes	24 (92.3)	35 (87.5)	p = 0.535	37 (86.1)	21 (100)	p = 0.072	13 (76.4)	28 (93.3)	18 (94.7)	p = 0.131
	No	2 (7.7)	5 (12.5)		8 (13.9)	0 (0)		4 (23.5)	2 (6.67)	1 (5.26)	
Psychological (%)	Yes	22 (84.2)	32 (80.0)	p = 0.635	34 (79.1)	19 (90.5)	p = 0.256	12 (70.1)	26 (86.7)	16 (84.2)	p = 0.370
	No	4 (15.4)	8 (20.0)		9 (20.9)	2 (9.5)		5 (29.4)	4 (13.3)	3 (15.8)	
Social (%)	Yes	23 (88.5)	26 (65.0)	p = 0.033	31 (72.1)	17 (80.9)	p = 0.442	12 (70.6)	21 (70)	16 (84.2)	p = 0.499
	No	14 (35.0)	26 (65.0)		12 (27.9)	4 (19.0)		12 (29.4)	9 (30)	3 (15.8)	

* Fisher's exact test.

Table 5.4: Type of SATp Needs Reported by Time

	Problem	**Baseline**	**1 Month**	**2 Months**	**3 Months**	**4 Months**	**5 Months**
Type of SATp problems identified [n]	Physical	[53] (1) Reference	[54] OR: 1.23 CI: (0.76–1.40) p = 0.34	[55] OR: 1.22 CI: (0.69–1.3) p = 0.47	[57] OR 1.55 CI: (0.85–2.83) p = 0.15	[56] OR: 1.55 CI: (0.80–2.36) p = 0.25	[56] OR: 1.36 CI: (0.80–2.36) p = 0.25
	Psychological	[53] (1) Reference	[44] OR: 0.4 CI: (0.34–0.89) p < 0.01	[46] OR 0.49 CI: (0.32–0.76) p < 0.01	[45] OR: 0.56 CI: (0.35–0.90) p = 0.02	[44] OR: 0.52 CI: (1.12–0.16) p = 0.01	[44] OR: 0.71 CI: (0.33–0.80) p < 0.01
	Social	[43] (1) Reference	[46] OR: 1.23 CI: (0.82–1.84) p = 0.31	[46] OR 1.23 CI: (0.90-1.94) p = 0.31	[47] OR 1.23 CI: (0.82–1.84) p = 0.15	[46] OR: 1.23 CI: (0.81–1.84) p = 0.31	[46] OR: 1.23 CI: (0.82–1.84) p = 0.31

5.5.4 Actions Taken by the GP

Participant self-reported GP consultations were validated through GP clinical notes for 45 of 57 participants (79%), with a 100% agreement between patient report and GP notes. In total, there were 117 GP consultations during which the SATp was presented, and a total of 78 GP actions recorded. Of these, 52 of 78 (44%) were prescriptions, 11 of 78 (14.5%) were investigations and six of 78 (7.7%) were referrals. Nearly all (n=76 of 78, 98%) participants were offered advice relating to the problems identified. Prescriptions (n=25) were mostly for antidepressants (nine of 25, 36%), sedatives (six of 25, 24%), analgesics (three of 25, 12%) and erectile dysfunction (two of 25, 8%). For those who visited a GP, the odds of receiving a prescription were similar for those reporting physical (OR 0.01, CI -1.14–1.14, $p = 0.90$) or psychological problems (OR 0.3, CI -0.49–1.21, $p = 0.41$).

5.6 Discussion

This study evaluated the feasibility and effect of a problem-identification intervention for participants with CRC. The various ways in which GPs addressed participants' problems across the five-month time frame were recorded. The success of the SATp intervention was assessed by the number of physical, psychological and social problems identified, changes in participants' number of problems and the number of problems addressed by the GPs. In this pilot study, all participants were able to complete the SATp throughout the study period, thereby demonstrating that the intervention was acceptable. The SATp was also able to identify patient problems, with 96% of participants reporting at least two problems, with a median of seven problems per patient.

There was a non-significant trend for reduction of physical and social problems, while psychological problems were significantly reduced ($p < 0.01$). The non-significant effect on physical outcomes may be partially explained by the relatively short study follow-up period. Some physical problems may have required radiological and laboratory investigations before a GP could provide treatment advice; thus, symptoms may have continued to be reported in the subsequent months. Similarly, social

problems, such as financial difficulties, require the involvement of other services and may take time to resolve, or may have been present prior to the cancer diagnosis. These factors may have contributed to the finding that the intervention appeared to have no statistically significant influence on these outcomes over the five-month timeframe.

Participants with physical problems tended to visit their GP more frequently ($p = 0.05$). This was confirmed particularly for participants with diarrhoea ($p = 0.03$). Other studies have reported similar findings that cancer patients are more likely to consult their GP more for physical symptoms than for other symptoms.[119] Although participants with physical problems used GP services more often than did those with psychological and social issues, most (17 of 25, 68%) prescriptions offered to participants were related to psychological problems, such as anxiety and depression. It is possible that some of the physical symptoms were manifestations of the underlying psychological distress that may be more evident during a doctor–patient consultation. [134] These results resonate with the results reported by Roorda et al. that, although patients with physical problems may be more likely to present in general practice, many also have psychological problems that are only identified during a consultation.[134]

Overall, there was a significant reduction in the number of participants who presented to a GP over the five months of the study. It is possible that the problems of these participants were addressed by the GP during the previous visits, or that participants whose problems were not being addressed ceased attending. Alternatively, the problems may have resolved on their own accord and patients became tolerant of the problem.

This study had the advantage of being prospective, with a participation rate of 75% (66 of 88). The characteristics of those who declined the study were similar to the participants, indicating that the results may be generalisable to other similar groups of participants. Moreover, this study was able to confirm that the patients continued to experience significant symptoms in the physical and psychosocial domains even years after completing treatment. Research has shown that a structured symptom checklist and screening tools are effective in eliciting the full range of problems for patients with other cancers.[193, 194] Although the SATp was structured, the response format was

meant to be a prompt to consultation to assist in a thorough exploration of possible problems.

A number of factors may have limited the influence of the intervention. The eligibility criteria may have excluded a group of participants with potentially higher or lower problems than those included. In addition, this study's measure was presented only in English, which meant that participants who were not fluent in English or unable to provide consent did not participate. Finally, this study was unable to assess whether participants not using the SATp intervention would have experienced similar outcomes. A randomised control trial is required to address this question.

5.7 Conclusion

This study showed that the SATp may be useful in primary care to facilitate identification of problems post–cancer treatment. In addition, it illustrates the possibilities of monitoring the long-term problems of CRC patients on a regular basis. This has value in general practice, where the majority of patients continue to receive ongoing care after being discharged from hospital.

Chapter 6: Supporting Patients Treated for CRC—A Video Vignette Study in General Practice (Study 4)

6.1 Summary

Background: Although under specialist care, patients who have been treated for CRC in Australia can consult their GP for advice about symptoms or side-effects at any time following treatment. However, there is no evidence that such patients are consistently advised by GPs, and patients experience substantial unmet needs for reassurance and advice.

Objective: This study sought to explore the influence of a variety of clinical and respondent characteristics on GPs' decisions to treat patients with treatment side-effects or symptoms of recurrence of CRC.

Methods: This was an email-based survey. Participants (GPs) viewed six video vignettes of actor-patients representing people who had been treated for CRC. The actor-patients presented problems that were a result of CRC treatment. The participants indicated their diagnosis and stated whether they would prescribe, refer or order tests based on that diagnosis. These responses were rated against the management decisions for those vignettes, as recommended by a team of experts in CRC.

Results: In total, 52 GPs consented and 40 (77%) completed the study. Most GPs completed diagnoses of CRC treatment side-effects or symptoms of recurrence that were consistent with the expert opinion. However, correct diagnosis was dependent on the type of case viewed. Compared to radiation proctitis, GPs were more likely to recognise peripheral neuropathy (OR 12.55, 95% CI 1.38–2.74) and erectile dysfunction (OR 21.98, 95% CI 2.24–36.84) and less likely to identify fatigue (OR 0.02, 95% CI 0.09–0.46). GPs who had worked more hours of direct patient care (OR 8.67, 95% CI 1.23–70.70, p = 0.03) and were more experienced (OR 9.78, 95% CI 1.18–8.84, p = 0.02) suggested management plans that were consistent with the expert opinion.

Conclusion: In this pilot study, years of experience and direct patient contact hours had a significant and positive effect on the successful management of patients. This study also showed promising results that management of the common side-effects of CRC treatment could be delegated to GPs. Such an intervention could support the application of shared care models of healthcare. However, a larger study that includes the management of side-effects in real patients must be conducted before this can be safely recommended.

6.2 Introduction

CRC is the second most commonly diagnosed adult cancer in Australia,[14] with one in 12 people in Australia developing CRC in their lifetime.[153] Most people with CRC survive more than five years and die of unrelated causes.[139] The treatment of CRC may include surgery, radiotherapy and chemotherapy. In the months and years following treatment, people may experience a number of troublesome side-effects, or symptoms and signs related to cancer recurrence. Many patients may experience bowel dysfunction, sexual dysfunction, urinary dysfunction and fatigue,[1] among other problems.

Post-treatment follow-up is provided in a secondary setting in some instances; however, this follow-up may only be for a short period for some patients, after which they are encouraged to see their GP about any ongoing problems.[31] Previous studies have demonstrated that cancer patients consult a GP routinely in the months and years after treatment for CRC, even for those with scheduled follow-up visits at the hospital.[35] CRC patients may contact their GP for a range of symptoms, such as radiation proctitis, urinary incontinence/urgency, fatigue, erectile dysfunction and symptoms of recurrence.[168] In order to address the needs of patients treated for CRC, GPs must be knowledgeable about the recommended treatment for the side-effects of CRC treatment, as well as the signs and symptoms that merit referral for further specialist treatment. This pilot video vignette study sought to explore the effect of a variety of clinical and respondent characteristics on GPs' decisions to treat patients with treatment side-effects or symptoms of recurrence of CRC.

6.3 Study Design and Participants

This video vignette study was developed to assess GP approaches to the management of CRC-related treatment side-effects or symptoms of recurrence. The videos were developed using scenarios of standardised patients (professional actors).[195] Using video vignettes as a method of data collection has been employed in health-related studies and to instruct students in schools of medicine.[196, 197] The usefulness of vignettes has resulted in their extensive use in medical school education,[198, 199] as well as in various studies that explicitly evaluate the quality of clinical practice in real-life settings and for comparative analysis among national healthcare systems.[195, 197, 200, 201] Video vignettes are suitable for cases in which ethical issues preclude recording patients' consultations or viewing patients' records,[202, 203] as in this study. They are also ideal for evaluations that require holding patient variation constant,[204, 205] so that participants are exposed to a similar stimuli, or for manipulating patient-level variables.[205, 206]

Participants were recruited from a convenience sample of 100 GPs across Australia who were members of the Curtin University Health Innovation Research Network. This is a free network formed to provide a safe and convenient venue for networking and exchanging information between primary healthcare practitioners (GPs, nurses, pharmacists, physiotherapists, dieticians, occupational therapists, podiatrists, psychologists, social workers, diabetes educators and so forth) and researchers with the common objective of improving primary healthcare. GPs were emailed invitations, and the original form of emails was supplemented with follow-up personal invitations to the invitees who did not initially respond. Participants were remunerated with AUD$50 for their contribution. Ethics approval was sought from the Curtin University Human Research Ethics Committee (HR 42/2012).

6.3.1 Development of the Survey: Delphi Process

Six video vignettes were developed to present potential side-effects related to treatment for CRC or the features of cancer recurrence (see multimedia Appendix 6.1 for an exemplar). The range of scenarios was based on the most common side-effects reported by CRC patients. The identification and validation of these side-effects is reported in a different phase of this project (see chapter 3).[33] Each vignette depicted a patient with clear indications for specific management, including referral, prescription, reassurance and/or investigation. The vignettes were developed by four GPs, a radiation therapist, a medical oncologist and a surgeon. The expert panel also suggested the management of each case with details of prescription, referral for specialist treatment and laboratory investigation (see Table 6.1). Management suggestions were gathered using a Delphi technique discussed in chapter three of this thesis. The primary researcher coordinated the responses of the panel of experts, who were selected based on their areas of expertise (Medical oncologist, Colorectal Cancer Surgeon, General Practitioners, and Radiation therapist). The panellists were asked to give a reason for each of their responses. The responses were then assessed against the existing Australian guidelines for management of colorectal patients by a team of three researchers.[37] Where marked deviations from the guidelines were noted, experts were asked to provide reasons for their responses until a consensus was reached.
These categories for patient management were identified by the panellists and have also been used in several other studies to assess the role of GPs in the follow-up of cancer patients.[48, 188-191]

The vignettes were then prepared as a short video monologue by an actor-patient. The videos included an off-camera commentary by an actor-doctor describing relevant signs to be found during clinical examination. Participation in the study was via the internet. Information about the actor-patients' medical history, family history, medication history and physical assessment were offered at the onset of each video. The participants were then asked four questions after watching each video vignette:

1. What is your diagnosis?
2. Would you prescribe something? If so, what would you prescribe?
3. Would you refer the patient? If so, to whom?
4. Would you order tests? If so, which tests?

The survey was administered via web-based software (https://www.qualtrics.com/) approved by Curtin University. The six video vignettes were presented to each participant. Randomisation was not undertaken because each participating GP was expected to view the six scenarios. The survey was pilot tested on the four GPs who were involved in developing the scenarios to test for the participants' ease of access to web link to the survey, the functionality of the videos, the estimated time of completion and the data recording. Details of the administered survey are presented in Appendix 6.2.

Table 6.1: Specific Recommendations for the Management of Specific CRC Side-effects and Recurrence

Symptom	Action to be Taken by GP
Case 1: Peripheral neuropathy	Prescribe: Amitriptyline or low dose of carbamazepine. Health advice: Inform patient that there is potential that this may not improve or may improve slowly over time. If fingers are still numb at 12 to 18 months post-chemotherapy, there is a likelihood that it will be permanent. Refer back to oncologist for consideration of pregabalin.
Case 2: Erectile dysfunction secondary to lower anterior resection (LAR)	Prescribe: First-line therapy. The use of phosphodiesterase inhibitors is recommended. Refer: Refer the patient back to the hospital for further management, such as second-line therapy, such as penile self-injectable drugs, intraurethral alprostadil and vacuum devices. Link patient to support services.
Case 3: Urinary dysfunction secondary to LAR/radiation	Order tests: Do this to rule out cardiovascular causes. Refer: Refer patient to physiotherapist for physical exercise. Refer to the specialist for further neurogenic examination.
Case 4: Tumour recurrence	Order tests: Computed tomography (CT), magnetic resonance imaging (MRI) or positron emission tomography (PET) scans. Scanning and endo-rectal ultrasound (ERUS). Repeat PET scan, and undertake full blood examination and blood film, liver function test, and urea electrolytes and creatinine (UEC) test. Refer: Refer back to the oncologist for further management.
Case 5: Fatigue	Order tests: Assess for causes because management of cancer-related fatigue involves specific treatment for potentially reversible causes (such as treating anaemia or metabolic or endocrine abnormalities, as well as managing pain, insomnia, depression or anxiety). Take symptomatic measures when no obvious aetiology or reversible cause can be identified. Prescribe: Psychostimulants. For patients with severe fatigue for whom non-pharmacologic methods do not resolve fatigue, and anaemia and other medical conditions and symptoms causing fatigue are controlled, a therapeutic trial of a psychostimulant (methylphenidate or modafinil) is a reasonable option.

Symptom	Action to be Taken by GP
Case 6: Chronic radiation proctitis	Order tests: Attend visual inspection of lower bowel by proctoscopy, sigmoidoscopy and/or colonoscopy, and test for anaemia, full blood count and stool culture to rule out comorbidities. Prescribe: If true diarrhoea is established, use an antidiarrheal agent (often combined with stool bulking). Health advice: Anorectal dysfunction has its origin in nerve and muscle fibrosis, and may be ameliorated by pelvic floor exercises and bowel 're-training'. Refer: If (significant) bleeding develops or is confirmed, refer patient for endoscopic therapies, such as thermal coagulation therapy or surgical therapies. Undertake proctectomy or diversion colostomy if the condition worsens.

6.4 Sample Size and Statistical Analysis

The main aim of this study was to evaluate the treatment GPs offer to standardised patients presenting with side-effects from CRC treatment or symptoms of recurrence. Each GP reviewed the same set of six video vignettes and responded to the four binary (yes/no) questions above regarding diagnosis, prescribing, referral and tests. Each of these four questions were analysed in a separate GEE model, with the binary response as the dependent variable, and the subject named as the random effect. The GEE model is appropriate for this design because it considers the correlation between responses from the same GP (across the six vignettes).

It was difficult to determine the estimated sample size required to give adequate power to detect associations with the independent variables, but it depends on the expected response proportions (such as the proportions of positive responses), and the correlations between responses belonging to the same respondent. In the absence of pilot data on which these quantities may have been estimated, a sample of 40 GPs was sought (who would provide 240 observations in total). This projected number cannot be mathematically justified in the absence of pilot data. However, in a standard regression model, a sample of 120 uncorrelated measurements should be adequate to identify an independent variable exhibiting a moderate effect size with 80% power.[207] It was assumed that doubling the number of observations would be adequate to compensate for the internal correlations in the dataset.

Each of the GEE models initially included the following independent variables: age, years of GP experience, recognised speciality qualification with the Fellows of the

Royal Australian College of General Practitioners (FRACGP), number of patient consultations per week, and patient consultation hours per week**.** A backwards elimination method was used to arrive at the final model. This method involved dropping the least significant variable, one at a time, until all variables remaining in the model were significantly associated with the outcome. The SPSS Version 21 software was used to perform the analysis and, following convention, a p-value < 0.05 was taken to indicate a statistically significant association in all tests.

6.5 Results

6.5.1 Demographics

In total, 52 GPs consented to participate in the project and 40 completed the study. Those who participated in the study were younger than general Australian GPs (mean age of 36.9 years v. 50.5 years) and a greater proportion were females (58.0% v. 39.1%) and registrars (32.7% v. 3.8%). The demographic details of the respondents are shown in Table 6.2.

Table 6.2: Participants' Demographic Information

Characteristics (N = 52)	Study Sample	National Population a Mean %
Demographics		
Age (years)—mean (SD)	36.9 (10.5)	50.5
Years of GP experience—mean (SD)	7.0 (9.7)	
Sex—n (%)		
Male	22 (42.0)	60.9
Female	30 (58.0)	39.1
Registrars (GPs in training)—n (%)	17(32.7)	3.8
Fellows of the Royal Australian College of GPs—n (%)	28 (53.8)	56.8
Practice demographics		
Practice accredited—n (%)	52(100%)	88.6
Clinic remoteness—n (%)		
Major city	36 (69.2)	71.1
Non-major city	16 (30.8)	28.9
Clinic location—n (%)[b]		
Capital	27 (51.9)	
Other metropolitan	14 (26.9)	
Large rural	6 (11.5)	
Small rural	4 (7.7)	
Remote centre	1(1.9)	
GP position in the practice—n (%)		
Principal	8 (15.4)	
Non-principal	35 (67.3)	
Others	9 (17.3)	
Patient consultations		
Patient consultations per week—n (%)		

Characteristics (N = 52)	Study Sample	National Population a Mean %
< 100	22 (42.3)	
100–149	21(40.4)	
≥ 150	9 (17.3)	
Patient consultations hours per week—n (%)		
< 11	10 (19.2)	1.2
11–20	4 (7.7)	12.2
21–40	24 (46.2)	53.0
41–60	14 (26.9)	33.5
Non-English consultations—n (%)		
No	45(86.5)	
Yes	7 (13.5)	24.5

[a] Sourced from national data when available.[208] [b] Classification based on rural, remote and metropolitan area (RRMA) classification.[209]

6.5.2 Diagnosis Consistent with Expert Opinion

The colorectal cancer video vignettes were presented 240 times in the study (40 GPs x 6 vignettes). Of the 240 diagnoses made by the GPs, an average of 168/240, 70% (range 35–95%) were consistent with the expert diagnosis. This consistency was observed more for erectile dysfunction (38/40, 95%), peripheral neuropathy (36/40, 90%) and tumour recurrence (31/40, 76%), compared to urinary dysfunction (23/40, 58%) and cancer-related fatigue (14/40, 35%). A higher proportion of correct diagnoses were made by GPs who worked more than 60 patient care hours per week (15/18, 83%), those who held a GP fellowship (101/138, 73%), and those who had less than 10 years of experience (1–2 years 71/96, 74%; 3–10 years 53/72, 74%).

A multivariate GEE analysis was carried out to determine whether a correct diagnosis depended on the case itself, or characteristics of the GP. There were some statistically significant differences in the diagnosis of the cases. Compared to radiation proctitis, GPs were more likely to identify cases with chemotherapy-induced peripheral neuropathy [OR 4.43, 95% CI 1.41–13.96, p=0.01] or erectile dysfunction [OR 9.70, 95% CI 2.48–38.03, p=0.001], but were less likely to recognise chemotherapy-induced fatigue [OR 0.19, 95% CI 0.08–0.44, p=0001]. Also, younger GPs (<30 years of age) [OR 2.64, 95% CI 1.12–6.22, p=0.03] and those who held a GP fellowship [OR 3.26, 95% CI 1.62–6.62, p=0.000] were more likely to identify cases consistent with the expert opinion. The demographic characteristics of the GP did not have any significant influence on their ability to recognise colorectal cancer treatment side effects or

symptoms of recurrence. Details of the factors associated with correct diagnosis are displayed in Table 6.3.

Table 6.3: Factors Associated with a Diagnosis Consistent with Expert Opinion

Outcome	Variable	n/N (%)	Odds ratio	95% CI	p-value
Diagnosis	**Age**				
	31 or older	103/156 (66)	1 (reference)		
	30 or younger	67/84 (80)	2.64	1.12–6.22	0.0262
	Years of practice				
	1–5	101/132 (77)	1 (reference)		
	5 or more	69/108 (64)	0.42	0.20–0.87	0.0189
	GP holds a fellowship				
	No	69/102 (68)	1 (reference)		
	Yes	101/138 (73)	3.26	1.62–6.54	0.0009
	Case vignette				<0.0001*
	1: Peripheral neuropathy	36/40 (90)	4.43	1.41–13.96	0.0110
	2: Erectile dysfunction	38/40 (95)	9.70	2.48–38.03	0.0011
	3: Urinary dysfunction	23/40 (58)	0.54	0.20–1.46	0.2227
	4: Tumour recurrence	31/40 (78)	1.55	0.48–5.06	0.4663
	5: Cancer-related fatigue	14/40 (35)	0.19	0.08–0.44	0.0001
	6: Radiation proctitis	28/40 (70)	1 (reference)		

*p-value for the variable as a whole.

Note: the dependent variable was a correct response. For example, in the first analysis, respondents who were aged 30 or younger were significantly more likely (OR 2.64) to give a correct diagnosis than the older participants. The numbers in the third column

6.5.3 Management Consistent with Expert Opinion

The GP management of the cases according to expert opinion was categorised into three domains: (i) referrals, (ii) prescribing and (iii) ordering tests.

6.5.3.1 Referrals

Of the 200 observations made by the GPs to correctly refer cases, only 43% (range 18–60%) were consistent with expert opinion. Most referrals were inconsistent with

the expert opinion. This inconsistency was greater for erectile dysfunction, radiation and peripheral neuropathy, with only 18% (7 of 40), 36% (15 of 40) and 43% (17 of 40) correctly referred, respectively. Similarly, only 38% (15 of 40) of referrals made by GPs who worked more than 60 patient care hours per week, and 33% (26 of 80) of those made by GPs who had one to two years of experience, were consistent with expert opinion.

The results of a regression analysis revealed that only the number of patient care hours worked by a GP per week influenced GPs' decisions to refer. Compared to GPs who worked more than 60 hours, GPs who worked 21 to 40 hours were more likely (OR 8.67, 95% CI 1.23–70.70, p = 0.03) to make referrals that were consistent with the expert opinion. The type of case viewed did not have any significant effect on a GP's decision to refer. Details of the factors associated with correct referrals are displayed in Table 6.4.

6.5.3.2 Prescribing

Of the 160 observations made by the GPs to correctly prescribe, only 39% (range 29–70%) of the prescriptions were consistent with the expert opinion. The only cases with a higher proportion of GPs who gave prescriptions that were consistent with expert opinion were erectile dysfunction (28 of 40, 70%) and radiation proctitis (26 of 40, 65%).

The results of the regression showed that GPs with more years of experience were more likely to offer a prescription that was consistent with the experts. Compared to doctors with three to 10 years of experience, doctors with more than 11 years were seven times more likely to give a prescription consistent with the expert opinion (OR 7.11, 95% CI 2.08–24.38, p = 0.001). Similar results were observed for GPs with a higher patient load per week. Compared to GPs who attended less than 100 patients per week, GPs who attended more than 150 patients had a 32% chance to offer prescriptions that were consistent with expert opinion (OR 0.32, 95% CI 0.12–0.84, p = 0.021). In addition, GPs had 16% chance to prescribe correctly for cases of peripheral neuropathy (OR 0.16, 95% CI 0.06–0.45, p = 0.000) than for radiation

proctitis. Details of the factors associated with correct prescription are displayed in Table 6.4.

6.5.3.3 Ordering Tests

Of the 160 observations made by the GPs to order tests, most were consistent with the expert opinion. At least 50% of the observations were consistent (average 36%, range 10–85%). This consistency was observed more for fatigue (33 of 40, 83%) and tumour recurrence (32 of 40, 80%) than for radiation proctitis (4 of 40, 10%) and urinary dysfunction (16 of 40, 40%). Fifty per cent (6 of 12) of tests ordered by GPs who worked more than 60 patient care hours per week, 64% (23 of 36) of those who worked in practices that had more than 150 consultations per week, and 58% (28 of 48) who had more than 11 years of experience were consistent with the expert opinion.

The regression analysis results showed that, compared to radiation proctitis, GPs were more likely to order tests for urinary dysfunction (OR 13.6, 95% CI 1.63–32.1, $p = 0.01$), tumour recurrence (OR 188.7, 95% CI 11.8–224.8, $p < 0.001$) and fatigue (OR 149.0, 95% CI 12.2–305.8, $p < 0.001$). Several demographics also influenced GPs' decisions to order tests. GPs with one to two years (OR 13.2, 95% CI 1.42–12.98, $p = 0.01$) and more than 11 years (OR 9.78, 95% CI 1.18–8.84, $p = 0.02$) of experience were more likely to order correct tests than were GPs with three to 10 years of experience. In addition, GPs with 21 to 40 hours (OR 0.12, 95% CI 0.10–0.93, $p = 0.04$] and 41 to 60 hours (OR 0.07, 95% CI 0.10–0.69, $p = 0.01$) of direct patient care were less likely to order tests that were consistent with the expert GPs than were GPs with more than 60 hours. Details of the factors associated with the correct ordering of tests by GPs are displayed in Table 6.4.

Table 6.4: Factors Associated with Management Consistent with Expert Opinion

	Referral			Prescription			Tests		
	Correct		OR (95% CI), p-value	Correct		OR (95% CI), p-value	Correct		OR (95% CI), p-value
	N	%		N	%		N	%	
GP years of practice									
1–2 years	26/80	33	0.16 (0.09-1.08), 0.06	29/64	45	2.15 (0.62-7.49), 0.23	35/64	55	13.2 (1.42-12.98), 0.01
3–10 years	30/60	50	1 (Reference)	14/48	29	1 (Reference)	22/48	46	1 (Reference)
11+ years	30/60	50	0.54 (0.16-2.56), 0.54	22/48	46	7.11 (2.08-24.38), 0.001	28/48	58	9.78 (1.18-8.84), 0.02
Total	86/200	43		65/160	39		85/160	36	
GP holds a fellowship									
No	30/85	35	1.75 (0.53-3.11), 0.57	33/68	49	0.53 (0.19-1.49), 0.23	35/68	51	5.42 (0.89-5.26), 0.09
Yes	56/115	49		32/92	35		50/92	54	
Total	86/200	43		65/160	39		85/160	36	
Number of patients seen in the practice/week									
Less than 100	38/75	51	1 (Reference)	27/60	45	1 (Reference)	30/60	50	1 (Reference)
100–149	35/80	44	0.51 (0.17-1.77), 0.50	25/64	39	0.48 (0.17-1.41), 0.18	32/64	50	1.27 (0.44-2.85), 0.81
150–199	13/45	29	0.4 (0.21-1.74), 0.35	13/36	36	0.32 (0.12-0.84), 0.021	23/36	64	5.58 (0.87-8.14), 0.08
Total	86/200	43		65/160	39		85/160	36	
GP direct patient care hours/week									
Less than 11	24/50	48	5.10 (0.69-55.6), 0.22	17/40	43	0.18 (0.04-0.82), 0.02	22/40	55	0.46 (0.21-1.94), 0.43
21–40	45/95	47	8.67 (1.23-70.7) 0.03	31/76	41	0.17 (0.04-0.70), 0.01	38/76	50	0.12 (0.10-0.93), 0.04
41–60	15/40	38	3.42 (0.47-27.6), 0.22	11/32	34	0.21 (0.05-0.92), 0.04	17/32	53	0.07 (0.10-0.69), 0.01
More than 60	2/15	13	1 (Reference)	6/12	50	1 (Reference)	8/12	67	1 (Reference)
Total	86/200	43		65/160	39		85/160	36	
Age	-	-	1.6 (0.09-1.08), 0.62	-	-	0.96 (0.92-1.00), 0.05	-	-	
Cases									
Case 1: Peripheral neuropathy	17/40	43	1.78 (0.57-2.8), 0.56	11/40	28	0.16 (0.06-0.45), 0.000	n/a	n/a	n/a
Case 2: Erectile dysfunction	7/40	18	0.15 (0.98-1.03), 0.06	28/40	70	1.30 (0.43-3.90), 0.64	n/a	n/a	n/a
Case 3: Urinary dysfunction	23/40	58	6.17 (0.93-6.78), 0.07	n/a	n/a	n/a	16/40	40	13.60 (1.63-32.14), 0.01
Case 4: Tumour recurrence	24/40	60	7.17 (0.97-8.16), 0.06	n/a	n/a	n/a	32/40	80	188.67 (11.77-224.80), < 0.0001
Case 5: Fatigue	n/a	n/a	n/a	0/40	0	n/a	33/40	83	149.90 (12.24-305.75), < 0.0001

	Referral			Prescription			Tests		
	Correct		OR (95% CI), p-value	Correct		OR (95% CI), p-value	Correct		OR (95% CI), p-value
	N	%		N	%		N	%	
Case 6: Radiation proctitis	15/40	36	1 (Reference)	26/40	65	1 (Reference)	4/40	10	1 (Reference)
Total	86/200	43		65/160	39		85/160	36	

Key: n/a—based on the experts' opinion, this item was not considered relevant to the management of the specific case.

6.6 Discussion

This study explored the effect of a variety of clinical and respondent characteristics on GPs' decisions to treat patients with treatment side-effects or symptoms of recurrence of CRC. Peripheral neuropathy, fatigue, bowel dysfunction, urinary dysfunction, tumour recurrence and sexual dysfunction are common presentations of patients with CRC in general practice.[50] This study's data indicate that the GPs correctly diagnosed most of these conditions, with the exception of fatigue. Compared to radiation proctitis, the GPs were less likely to recognise fatigue. This could be expected because, in most cases, fatigue presents as a manifestation of other underlying conditions and is difficult to diagnose.[210] The results of the regression analysis alluded to this scenario. Although almost three quarters the participating GPs did not recognise cancer related fatigue, the regression results showed that they ordered tests to explore underlying conditions, which was consistent with the expert suggestions.

However, suggestions for management plans for these conditions were not consistent with expert opinion in all the applicable categories of management (referrals, prescribing and ordering tests) for the specific cases. The regression analysis led to the conclusion that, compared to radiation proctitis, tumour recurrence, fatigue and urinary dysfunction were more likely to be managed as per the experts. There were marked deviations from the experts' suggestions for erectile dysfunction and peripheral neuropathy. For example, for erectile dysfunction, GPs were less likely to refer this case back to the specialist, but did offer appropriate medication. There were similar deviations from expert management for peripheral neuropathy and urinary dysfunction. Such deviations from expert opinion have been reported previously in similar studies with prostate cancer patients.[48] The differences in management between the participants and expert panel were less marked for the management of tumour recurrence. This could be expected because most patients present to a GP before cancer diagnosis[184] or present with symptoms of recurrence even when receiving ongoing management by their specialist.[35] Thus, it is plausible that the GPs were well experienced in recognising and making appropriate decisions related to tumour recurrence.

The regression analysis also suggested that there were other influential variables affecting the management of these conditions. The results indicated influence from some of the demographic characteristics of the participants—specifically, the number of patient contact hours and years of experience. GPs with one to two years and more than 11 years of experience were more likely to manage patients according to expert opinion. This was not unexpected for patients treated for CRC because many of these problems are likely to present infrequently when patients are still receiving follow-up from their specialist, and some doctors may not have encountered them previously. However, it was surprising that less experienced GPs (one to two years of experience) were indicated. In this case, it is plausible that their patient contact hours were more than their counterparts, hence they more likely to have encountered similar cases. Also the currency of training may have contributed to their level of awareness of CRC treatment related problems and their management.

A number of approaches have been reported in the literature to promote the consistent and reliable management of chronic conditions in primary care.[211, 212] A few of these have focused specifically on the knowledge of GPs,[48] while others have reported that attitudes and beliefs are important in the context of a cancer diagnosis.[213] These issues were not evaluated in this study. For example, this study was unable to report the participants' attitudes towards the management of patients following treatment, and whether they felt this role extended to investigating and treating conditions that may have resulted from specialist treatment. In addition, this study could not identify any practitioners with specialist training in CRC. However, all participants were working as GPs when they participated in this study, and it is reasonable to assume that there were a negligible number with specialist training in a specific cancer.

This pilot study had a modest sample size of 240 observations—a number that was assumed to be adequate to estimate the proportion of occasions on which at least one problem was correctly identified or managed with reasonable precision (approximately ± 10%). This was not true of all management modalities. In some cases, the number of observations was very low, as evidenced by the wide confidence limits shown in Table 6.3. Therefore, a much larger and randomised study is required to robustly test this study's objectives.

6.7 Conclusions

In this pilot study, direct patient contact hours had a significant and positive effect on the successful management of patients. In addition, this study showed promising results that management of the common side-effects of CRC treatment could be delegated to GPs. Such an intervention could support the application of shared care models of healthcare. However, a larger study that includes management of the side-effects of real patients must be conducted before this can be safely recommended.

Chapter 7: Discussion and Conclusions

7.1 Overview of the Chapter

This chapter provides a summary of the key findings, as reported in Chapters 3 to 6. It also includes an exploration of how the research questions and intentions were addressed via these studies. The overall intention of this thesis was to assess whether patients treated for CRC would benefit from GP support, even with ongoing specialist care. To address this intention, a series of studies were undertaken.

1. First was the development of a patient-completed self-assessment tool (SATp) that included the most common problems reported by CRC patients (Study 1 in Chapter 3). This study identified from the literature the most commonly reported problems encountered by CRC patients following treatment. Through a Delphi method, these problems were validated by two expert panels, including a group of CRC patients who had completed treatment, and experienced CRC healthcare professionals. Test–retest reliability was assessed by administering SATp to a subset of participants who agreed to fill it out on two occasions, approximately two weeks apart. The SATp was then subjected to readability testing. The final items were structured into physical, social and psychological problems based on a framework reported by Pigott et al.[29] and Bonevski et al.[145] The SATp was employed by the CRC patients to aid GP consultation.

2. The second study explored the factors that may influence CRC patients' intentions to seek health advice from a GP (Chapter 4). In this study, participants completed a questionnaire that was developed based on the TPB, and CRC patients' intentions to attend a GP for care. The influence of a variety of TPB constructs (attitude, influence of important others, perceived control and barriers) and respondent characteristics on patients' decisions to seek help from a GP were reported. The results of this study were presented as barriers to and facilitators for seeking health advice from a GP.

3. Third was an evaluation of the feasibility and effect of a problem-identification intervention for participants with CRC (Chapter 5). In this prospective study, a trial of SATp (developed in Study 1) was undertaken. Participants were provided with a booklet including the SATp for them to keep a monthly record of problems they experienced, and to aid GP consultation. A baseline assessment was done, followed by monthly evaluations for five subsequent months. The Glasziou and Haynes model of evidence-based medicine that outlines the path from research to improved health outcomes[54] was used as the theoretical framework to guide deployment of the intervention. The success of the SATp intervention was assessed via the number of physical, psychological and social problems identified, changes in the participants' number of problems, and the number of problems addressed by the GPs.

4. Finally, this project explored the effect of a variety of clinical and respondent characteristics on GPs' decisions to treat patients with treatment side-effects or symptoms of recurrence of CRC (Chapter 6). This was an email-based survey. Participants viewed video vignettes of actor-patients representing people who had been treated for CRC. The actor-patients presented problems that were resultant from CRC treatment. The participants indicated their diagnosis and stated how they would treat the problem. These responses were then rated against the management decisions for those vignettes recommended by a team of experts in CRC.

7.2 Principal Findings of the Thesis and How They Answered the Research Questions

Figure 7.1 provides a schematic representation of the relationship between the various studies undertaken and the research questions.

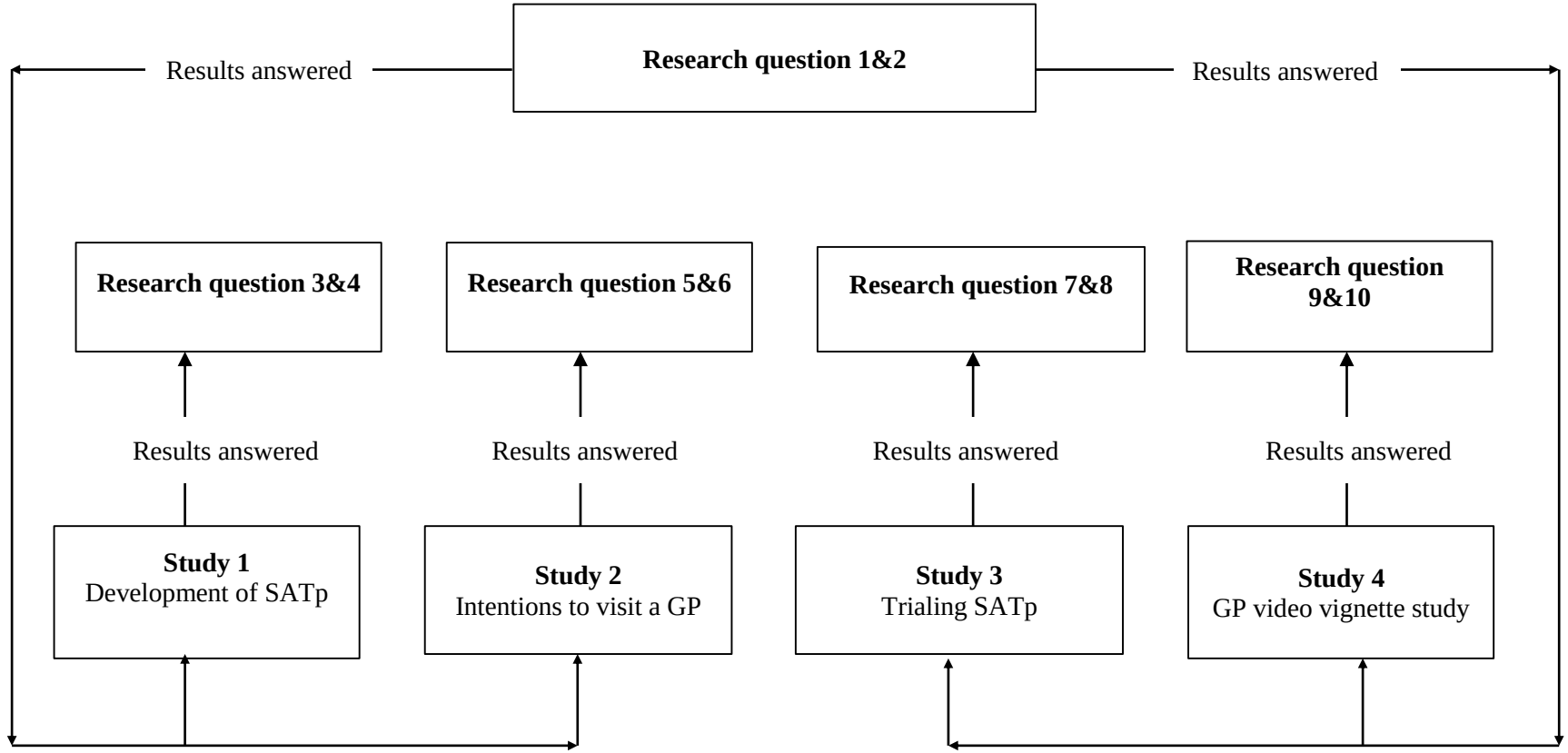


Figure 7.1: Relationship between the Various Studies and Research Questions and Intentions

7.2.1 Study 1: Development of the SATp to Assess Problems that Patients may Experience Following Treatment for CRC

This study answered Research Questions 3 and 4:

> RQ 3. Could a user-friendly, patient completed data collection tool (SATp) be developed to assess problems that patients may experience following treatment for CRC?
>
> RQ 4. Is the SATp a reliable and valid data collection tool for assisting patients to discuss issues associated with their CRC treatment with their GP?

According to the seven criteria for needs-assessment tools outlined in Chapter 3, a tool is effective if it:

1. contains physical, psychological and social aspects to measure multiple domains of CRC care[142, 146]
2. uses a self-reporting approach to facilitate direct and comprehensive assessment of subjective health needs[142]
3. measures the needs in a defined temporal context[29]
4. demonstrates validity and reliability through expert review, test–retest and pilot testing to provide a sound basis for comparison[145]
5. embraces a user-friendly response framework[145]
6. is 'system-friendly' by minimising the patient and staff time required to complete and review[142]
7. provides an opportunity for clinicians to link patients to services.[29]

The SATp fulfilled all the criteria outlined by these studies. The SATp comprehensively evaluated a wide range of problems specific to CRC patients. This tool integrated physical, psychological and social aspects to measure multiple domains of CRC care. Similar studies done among breast cancer patients have emphasised the use of such domains to assess patients' problems following cancer treatment.[146] The participants were asked to report issues they may have experienced during the previous four weeks. This ensured that the needs were measured within a defined time-based context.[29]

The results of this study indicated that the SATp fulfils the current scientific criteria for acceptability, internal consistency, validity and usability. Through an internal consistency process, it was possible to demonstrate evidence for a strong, structurally reliable SATp tool as reported in chapter 3.

Throughout the developmental phases, opinions from the expert team and from patients were incorporated to balance the two perspectives that might be discordant. The findings from consultation with experts and patients suggested similarity in ranking for most of the items. However, higher rankings were reported for physical symptoms by experts and for social needs by patients. These findings are consistent with other studies showing an emphasis by experts on symptom management and by patients on other type of needs.[27, 142]

In terms of need prevalence, this study's results seem to suggest the universal nature of need experiences. The pattern of need prevalence in the current study seems substantially similar to those reported by previous studies. Consistent with studies indicating psychosocial problems as the most prevalent needs, three—fear of recurrence (53%), insomnia (53%) and housework difficulties (45%)—of the top five needs were found in the psychological and social domains.[143, 214] According to Hodgkinson et al.,[143] psychological comorbidity results in a fourfold increase in unmet needs among cancer patients.

7.2.2 Study 2: Predicting Study Participants' Intentions to Attend a GP Following CRC Treatment

This study answered Research Questions 5 and 6:

> RQ 5. Are personal attitude, perceived control/barriers, and the influence of other people independently associated with CRC patients' intentions to attend a GP for future health advice about their CRC problems?
>
> RQ 6. Do patients' demographics and clinical characteristics, such as the presence of an existing chronic illness, influence their intentions to visit a GP for health advice about their CRC problems?

This study used the TPB to explore factors that may influence CRC patients to seek health advice from a GP about their CRC-related problems. The TPB suggests that intention immediately precedes behaviour because it reflects the person's level of motivation and desire to perform a certain action. Intention is determined by attitudes, subjective norms and perceived behaviour control constructs.[177] PBC is the perceived opportunities and resources available for performing the behaviour, and may directly lead to the behaviour if it accurately reflects actual control. Attitude is viewed as the perceived advantages and disadvantages of performing the behaviour. Subjective norms are the perceived social pressures (such as important people) that influence an individual to perform the behaviour or not.[62]

This study sheds light on how attitude, subjective norms and PBC influence CRC patients' intentions to engage with a GP following cancer treatment. Specifically, significant associations between attitude, subjective norms, the presence of a chronic illness, and future use of GP services by participants were documented. This study also assessed attitude factors, such as 'attending a GP about CRC is likely to: (i) detect problems and side-effects early and (ii) reassure me', and subjective norms factors, such as the influence of family, specialists and cancer nurses on attendance.

Although this study recruited participants via hospital cancer clinics, previous studies have reported that prediction of intentions by attitudes and subjective norms can be strongest in studies that recruit via GP practices.[57] The large attitude–intention relationship for seeking health advice from a GP suggests that individuals may value visits to their GP more than visits to settings such as hospitals. The subjective norm–intention association for GP settings may be a reflection of participants having family who attend the same practice and/or having a good relationship with the GPs at their local practice. However, this finding regarding subjective norm emerging as a significant predictor of intention contrasts to other studies predicting CRC patients' intentions to attend screening programs.[215] It is possible that this might be related to the way in which the subjective norm was measured. A more reliable, multi-item scale might have strengthened the relationship of subjective norm with intention.[57, 215]

The regression analysis also suggested that the combined effect of these factors accounted for a strong influence (43.3%) on future intention to attend follow-up visits. Attitude and the presence of a chronic illness were responsible for 23.3% and 12.8% of this variance, respectively. Analysis of the regression models provided a different picture regarding the PBC construct. Although personal attitude was strongly associated with patients' intentions to seek health advice from a GP, PBC did not account for significant variance on future use of primary care services for CRC follow-up care. This finding contrasts research among CRC patients attending physical exercise sessions, which suggests that PBC has a significant influence on intention.[60, 179]

PBC factors such as affordability, travel and ease of booking an appointment with a GP had limited influence on patients' intentions, which was not anticipated with this group as the majority were retired 47/66 (71.2%). Noting that the mean age of participants was 69.2 (SD 9.9) years, PBC may not have had an influence because patients in this age category in Australia receive government-subsidised GP consultations and travel concessions. However, other studies on attendance to screening programs align with this study's findings that perceive behaviour control as a relatively unimportant predictor of attendance.[57]

Other studies show that CRC patients living alone have a more positive attitude towards follow-up care than do those who are married or living with a sibling or friend.[183] However, this study showed that socio-demographic characteristics, such as age and marital status, had no effect on patients' attitudes towards visiting a GP for health advice about their CRC-related problems. The only statistically significant association with socio-demographic and clinical characteristics was that patients with a coexisting chronic illness had a more positive attitude towards attending a GP ($p < 0.05$). This may be expected because 30 to 60% of CRC survivors aged 70 years or older have a coexisting chronic illness[117] and are more likely to attend primary care for ongoing follow-up.

7.2.3 Study 3: A trial of the Self-Assessment Tool (SATp Intervention)

This study answered Research Questions 7 and 8:

> RQ 7. Can the SATp help identify physical, psychological and social problems related to CRC treatment?
>
> RQ 8. If patients present the SATp to their GP, would this facilitate discussions about any physical, psychological and social problems associated with their CRC treatment?

This study evaluated the feasibility and influence of a problem-identification intervention for participants with CRC. Various ways in which GPs addressed participants' problems during the study period were recorded. The number of physical, psychological and social problems was recorded, and changes in the participants' number of problems over the five-month period were documented. The results of this study showed that the SATp tool was able to identify patient problems, with 96% of participants reporting at least two problems (a median of seven problems per patient). Research has shown that a structured symptom checklist and screening tools are effective in eliciting the full range of problems for patients with other cancers.[193, 194] Although the SATp was structured, the response format was meant to be a prompt to consultation in order to assist in a thorough exploration of possible problems.

There was a non-significant trend in reducing physical and social problems, while psychological problems were significantly reduced ($p < 0.01$). The lack of effect on physical outcomes may be partially explained by the relatively short study follow-up period. Some physical problems may have required radiological and laboratory investigations before a GP could provide treatment advice; thus, symptoms may have continued to be reported throughout the study period. These factors may have contributed to the finding that the intervention appeared to have no influence on these outcomes over the five-month timeframe.

Participants with physical problems visited their GP more frequently ($p = 0.05$) compared to those with social or psychological problems. Other studies have reported

similar findings that cancer patients are more likely to consult their GP more often for physical symptoms than for other symptoms.[119, 216] It is also possible that patients felt less compelled to seek health advice regarding psychological and social problems, rather than physical problems. Heins et al. reported that direct fear of cancer recurrence was rarely recorded as reason for a GP visit, even though participants had significant psychological morbidity.[216] Similarly, Mikkelsen et al. conducted a survey among cancer survivors and found that, although many experienced psychosocial problems—such as fear of recurrence of cancer or problems within the family—these problems were rarely discussed with the GP or other medical care providers.[217] However, Heins et al. stated that, when a clinician suspects psychosocial issues in a patient, they must take a proactive approach to discussing these problems.

This study was able to confirm that patients continue to experience significant symptoms in the physical and psychosocial domains even years after completing treatment. Although the sample size was modest and the prevalence of the reported symptoms may have been higher than for other CRC survivors in general, these results reaffirm the findings of several other studies of CRC survivors.[1, 21, 142, 218, 219]

7.2.4 Study 4: Approach to Managing CRC Treatment–related Side-effects and Symptoms of Recurrence: A Video Vignette Study in General Practice

This study answered Research Questions 9 and 10:

> RQ 9. Can GPs recognise the side-effects of CRC treatment or recurrence of CRC?
>
> RQ 10. Can GPs manage the side-effects of CRC treatment or recurrence of CRC, in accordance with experts' opinion?

This study explored the effect of a variety of clinical and respondent characteristics on GPs' decisions to treat patients displaying treatment side-effects or symptoms of recurrence of CRC. Six video scenarios were viewed by GPs, involving peripheral neuropathy, erectile dysfunction, urinary dysfunction, tumour recurrence, cancer-related fatigue and radiation proctitis. The GPs were asked to provide a diagnosis and

management plan based on the experts' opinion. This study indicated that GPs can recognise most of the conditions that were presented. However, GPs' suggestions for management plans for these conditions were not consistent with expert opinion in all the applicable categories of management (refer, test and prescribe). Such deviations from expert opinion have been reported previously in similar studies with prostate cancer patients.[220] The differences in management between the participants and expert panel were less marked for the management of tumour recurrence. This may be expected because most patients present to a GP before the cancer diagnosis,[184] or with symptoms of recurrence, even when receiving ongoing management from their specialist.[35] Thus, it is plausible that the GPs were well experienced in recognising and making appropriate decisions related to tumour recurrence.

7.3 Conclusions and Recommendations for Research and Practice

The review of the literature in Chapter 2 on the benefits of GP support for cancer patients indicated that research relating to the care of long-term cancer survivors in primary care is limited.[221] Clinicians, policymakers and researchers also acknowledge that long-term support for cancer survivors must be considered to ensure the optimal wellbeing of people with cancer during all stages of their complex disease journey.[38, 222-224]

Chapter 3 (development of the SATp) adds to this body of knowledge by demonstrating that CRC survivors have numerous health needs that must be addressed for many years after diagnosis. This thesis also indicates the role of GPs in supporting cancer patients. The literature reviewed in Chapter 2 made clear that general practice is the first point of contact for healthcare and advice, even for patients under the care of specialists.[164] Chapter 4 (predicting the intentions of patients to attend a GP) demonstrated that CRC patients trust their GPs to manage their problems following treatment. Chapter 5 (evaluating the feasibility and effects of problem-identification interventions in general practice) and Chapter 6 (approach to GPs managing CRC treatment side-effects) confirmed that general practice is well placed to provide support for people treated for CRC.

The findings of this research can be viewed in the context of Glasziou and Haynes model discussed in chapter one of this thesis.[54] According to Glasziou and Haynes, even with the best evidence available, there are substantial gaps between the evidence and the management patients receive. Further this model states that even when clinicians know and accept what to do, they often forget to act on the evidence. Omissions are more frequent for long-term and preventive issues because they are not the pressing focus of a consultation. [54] Patients on the other hand must contend with conflicting advice, adverse effects and sometimes a lack of ability to pay for the tests and treatments. Strategies must be trialled to encourage concordance. [54]

7.3.1 Evidence Identified by this Thesis Recommendations for Further Research

In Chapter 4 (predicting intentions of CRC patients to attend a GP), attitudes appear to be a strong predictor of patients' intentions to engage with a GP following CRC treatment. Consequently, to encourage engagement with general practice among CRC patients, interventions would be best advised to create awareness of the CRC services that general practice is able to provide. This will generate positive attitudes, rather than alter other TPB constructs, such as subjective norms or PBC. The large attitude–intention relationship suggests that a greater number of individuals made informed choices regarding attending a GP for health advice about their CRC needs.

The findings of this study may inform intervention efforts to transfer cancer care to GPs. Intervention efforts geared towards strengthening patients' awareness of the issues their GPs can manage may increase confidence in GPs to offer such support. Intervention efforts are likely to be most effective by tailoring programs to highlight how GPs can support follow-up care. In addition, it may be easier to transfer the care of cancer patients who already attend a GP for other chronic illnesses.

Given the importance of attitudes and presence of a chronic illness as predictors of intentions to engage with a GP, it is important for future research to assess the influence of the properties of attitude—such as levels of knowledge about the CRC services provided by GPs—on attitude–intention consistency. More research is required to investigate how individuals would react to invitations to attend a GP visit.

Other studies that have investigated the use of invitation to screening programs have shown that test context and location of recruitment suggest that invitations may be viewed differently depending on where the invitation comes from and the nature of the test.[57, 58, 225, 226]

Chapters 5 (a pilot evaluation of the feasibility and effect of a problem-identification intervention in general practice) found that it is feasible to address patients' problems following treatment via the support of a GP. The literature review in Chapter 2 found minimal body of evidence that suggested that this method of supporting patients was commonly used in practice. The lack of published documentation for this approach was hypothesised to result from the complex nature of these types of interventions, which challenge evaluation attempts in practice. Guidance from the Medical Research Council and other studies suggest that piloting is essential prior to large-scale evaluation and implementation of complex interventions, of which support care is an example.[227-229] During piloting, specific attention should be given to examining the feasibility, acceptability and potential outcomes of an intervention.[229] Therefore, a longitudinal pilot study of SATp intervention was undertaken and reported in Chapter 5 to confirm the utility of such an approach for CRC patients.

This pilot evaluation used an assessment tool (SATp) developed in Chapter 3. The results indicated that using SATp is effective in identifying patients' needs. These results align with other studies which confirm that using a structured symptom checklist or screening tool is effective in eliciting the full range of problems for patients with other cancers.[193, 194] The SATp was not only structured, but the response format was also intended to be a prompt to consultation in order to assist in a thorough exploration of possible problems by the GP.

The SATp intervention included a sample of patients who had completed treatment and those with Stages I to III CRC. This is likely to have contributed to the variability of the scores reported. To reduce this variability, ideally, subgroup analysis would be performed to determine whether the SATp intervention benefited patients with particular personal or clinical characteristics. However, the sample size of the study precluded this analysis. The ability to perform a subgroup analysis to reduce heterogeneity further supports the requirement for a larger study.

Relevant approaches have been tried in the past. Such approaches include using computer touchscreen technology to routinely screen patients' needs in 'real time', such as QIUCA-TOUCH (Quick, Individually Customised Assessment using Touchscreen),[230] the CONNECT intervention[231] and the Supportive Needs Screening Tool.[29] Oncology outpatients were screened for pain, distress and other common psychopathology using these methods, and then referred to appropriate services. Such interventions are useful for screening patients' needs following cancer treatment. The usability of these tools in primary care was not documented.

Chapter 6 (approach to managing CRC treatment–related side-effects and symptoms of recurrence—a video vignette study in general practice) found that GPs can recognise and manage most of the problems patients present following cancer treatment. Although peripheral neuropathy, fatigue, bowel dysfunction, urinary dysfunction, tumour recurrence and sexual dysfunction are common presentations of patients with CRC in general practice, not all of these symptoms were identified and treated as per expert opinion across all categories of management (referral to a specialist, order investigations and prescribe medications). For some of the symptoms, correct investigations were ordered but participants failed to suggest a referral back to the specialist for further management.

A number of approaches have been reported in the literature to promote consistent and reliable management of chronic conditions in primary care.[211, 212, 232] A few of these have focused specifically on the knowledge of GPs,[190] while others have reported that attitudes and beliefs are important in the context of a cancer diagnosis.[213] These issues were not evaluated in this study. For example, this study was unable to report the participants' attitudes towards the management of patients following treatment, and whether they felt that this role extended to investigating and treating conditions that may have resulted from specialist treatment. In addition, this study could not identify any practitioners with specialist training in CRC. However, all participants were working as GPs when they participated in this study, and it is reasonable to assume that there were a negligible number with specialist training in a specific cancer. This pilot study had a modest sample size of 240 observations—a number that was assumed to be adequate to estimate the proportion of occasions on which at least one problem

was correctly identified or managed with reasonable precision (approximately ± 10%). This was not true of all management modalities. In some cases, the number of observations was very low, as evidenced by the wide confidence limits shown in Table 6.3. Therefore, a much larger and randomised study is required to robustly test this study's objectives.

Overall, this thesis has demonstrated that using a screening tool (SATp) with appropriate support in place (general practice) is a viable method to support CRC patients with problems following cancer treatment. The reports of Study 3 showed that GPs can recognise and offer appropriate treatment for most of the side-effects of CRC treatment and for the symptoms of recurrence. However, more training is required for GPs to effectively treat all CRC treatment–related side-effects.

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Referencing copyright declaration

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Appendices

Appendix 2.1: Main Findings of the Studies Assessing Side-Effects of Colorectal Cancer Treatment

Type of Study and Study Setting	Author	Study Details	Side effects reported
RCT Norway	Holtedahl et al. 2005[42]	Cancer site: Multiple sites Length of follow-up: Six months Sample size: Int n = 41, hospital n = 50 Survey response rate: Int 88%, hospital 90%	The most prevalent concerns reported one year after diagnosis and treatment were fear of recurrence (68%), fatigue (67%), and sleep difficulties (48%)
RCT Denmark	Bergholdt et al. 2012[36]	Cancer site: Multiple sites Length of follow-up: 14 months Sample size: Int n = 486, hospital n = 469 Response rate: Overall response rate reported = 71%	Pt psychological distress: fear of recurrence The most commonly reported symptoms were fatigue (23%); physical discomfort (19%); stomach-ache was more frequent for survivors treated with chemotherapy (11%); diarrhoea radiotherapy (24%)
RCT UK	Lindsey I et al 2002 [236]	Cancer site: Rectum Sample size: Int n = 18, hospital n = 14 Length of follow-up: Not specified	- Male Sexual Dysfunction Loss of orgasm General dysfunction Erectile dysfunction Ejaculatory problems - Female Sexual Dysfunction Dyspareunia Vaginal dryness
Case Control Study Netherlands	Peeters et al 2005 [2]	Cancer site: Rectum Sample size: 597 Length of follow-up: 7 years	Bowel Dysfunction Clustering of BMs Night time BM Incontinence Pad wearing Inability to defer BM Diarrhoea Constipation
Prospective Cohort study United States	Schneider et al 2007[3]	Cancer site : Colon and Rectum Sample size : 474 Length of follow-up: 4 years	Urinary Incontinence (Surgery +/− Radiotherapy)

Type of Study and Study Setting	Author	Study Details	Side effects reported
			Urinary incontinence (38%), difficulties in bladder emptying (31%), need to void within two hours of voiding (70%), and need for protective pads (57%) Difficulty bladder emptying Bowel dysfunction frequency, urgency, evacuatory difficulties, and inability to differentiate stool and gas Diarrhoea Constipation Fear of recurrence
Retrospective cohort study Netherlands	Lange et al 2008 [237]	Cancer site: Rectum and colon Sample size 785 Survey response rate: Not specified	Urinary Incontinence (Surgery +/− Radiotherapy Difficulty bladder emptying, Need to void within 2 hrs Pad wearing
Prospective cohort study United States	Kurtz, M., et al 2002 [237]	Cancer site: Colon and Rectum Sample size: 211 Survey response rate: Not specified	26–44% of long-term CRC survivors continued to worry about cancer recurrence, symptoms as cancer indicators, getting a second malignancy, or future diagnostic tests. Cancer-related health worries were associated with anxiety and depression, with 24% of the survivors reporting depression scores that were high enough to need evaluation for clinical depression
Cross-sectional study United States	Haggstrom et al. 2009[50]	Cancer type: Colorectal cancer Sample size: n = 303 Survey response rate: Not specified	- sensory impairment of the peripheral nerves in a stocking-glove distribution o numbness, pain, paresthesias, dysesthesias, and changes in proprioception - urinary retention
Cross-sectional study United States	Kaley, T.J. and L.M. DeAngelis[238]	Cancer type: Colorectal cancer Sample size: n = 350 Survey response rate: Not specified	- Peripheral neuropathy

Appendix 2.2: Main Findings of the RCTs and Observational Studies Assessing the Importance of GP Involvement in Cancer Care

Type of Study and Study Setting	Author	Study Details	Main Conclusions
RCT Norway	Holtedahl et al. 2005[42]	Cancer site: Multiple sites Length of follow-up: Six months Sample size: Int n = 41, hospital n = 50 Survey response rate: Int 88%, hospital 90%	- QoL: No statistically significant difference in QoL between the intervention and hospital group - Patient satisfaction with care: Improved satisfaction after six months of follow-up
RCT Denmark	Nielsen et al. 2003[46]	Cancer site: Multiple sites Length of follow-up: Six months since diagnosis Sample size: Int n = 121, hospital n = 127 Questionnaire response rate: Int 78%, hospital 64%	- QoL: No statistically significant difference in QoL between the intervention and hospital group - Patient satisfaction with care: A statistically significant difference in the intervention group for: • feeling not being left in limbo: Int 65.49 (n = 65) v. hospital 58.55 (n = 77); p = 0.05 • inter-sectoral cooperation: Int 59.22 (n = 62) v. hospital 51.71 (n = 62); p = 0.05 (Statistical test used: Mann-Whitney U test)
RCT Denmark	Bergholdt et al. 2012[36]	Cancer site: Multiple sites Length of follow-up: 14 months Sample size: Int n = 486, hospital n = 469 Response rate: Overall response rate reported = 71%	- QoL: No statistically significant difference in QoL between the intervention and hospital group - Pt psychological distress: No statistically significant difference between the intervention and hospital group
RCT Norway	Augestad et al. 2013[168]	Cancer site: Colon Length of follow-up: 24 months Sample size: Int n = 55, hospital n = 55 Response rate: Overall = 75%	- QoL: There was a significant improvement in postoperative QoL (p = 0.003) at baseline, but no differences between groups revealed at the one-, three-, six-, nine-, 12-, 15-, 18-, 21- and 24-month follow-up appointments) - Recurrence: There were no differences in time to recurrent cancer diagnosis between Int and hospital groups (Estimated mean change for EORTC QLQ-C30 between the groups was calculated)
Cross-sectional study United States	Forsythe et al. 2012[133]	Cancer site: Breast and colon Sample size: PCPs n = 1,021, ONCs n = 1,130	- ONCs and PCPs reporting sole and shared provision of psychosocial care

Type of Study and Study Setting	Author	Study Details	Main Conclusions
		Survey response rate: Not specified	- Both PCPs and ONCs saw themselves as providers of psychosocial care. The PCPs were confident in providing psychosocial care to patients, while the ONCs reported shared provision of psychosocial care ($p < 0.001$) (Statistical test used: Mann–Whitney test)
Prospective longitudinal study Canada	Aubin et al. 2010[132]	Cancer site: Lung cancer Length of follow-up: 18 months Sample size: n = 395 Survey response rate: 56.8%	- Patient contact with family physician upon cancer diagnosis and during treatment, follow-up and terminal care - 92% of cancer patients had a regular family physician - Extent of family physician involvement in treatment decisions (% of patients): At baseline, only 16% of patients perceived a shared care pattern between their family physician and oncologists; however, this proportion increased with cancer progression to terminal care ($p < 0.001$) (Statistical test used: Cochran–Mantel–Haenszel test)
Retrospective cohort study Netherlands	Roorda et al. 2012[134]	Cancer site: Breast Sample size: Pts n = 185, Refgrp n = 585	- Annual healthcare use in primary care before diagnosis v. since diagnosis (%): Pts. with breast cancer had twice as many face-to-face contacts ($p < 0.001$) with the GP and a higher number of cancer-related medication prescriptions ($p < 0.01$) than did women from the Refgrp (Statistical test used: Mann–Whitney test)
Cross-sectional study United States	Haggstrom et al. 2009[50]	Cancer type: Colorectal cancer Sample size: n = 303 Survey response rate: Not specified	- Pt contact with PCP: 16% of CRC survivors saw PCP, while 60% saw ONC - Survivors most often seen by PCPs were more likely to have three or more medical comorbidities (70% v. 51%, $p = 0.012$) than survivors seen by specialist - Quality of care/content of follow-up: No significant specialty differences in patient-centred quality of follow-up cancer care

Note: hospital = control group, Int = intervention group (GPs involved in cancer care), Dx = diagnosis, ONC = oncologist, Pts = patients, Refgrp = reference group (women without breast cancer).

Appendix 2.3: Results Indicating Type of GP Involvement in Cancer Care

Type of Study and Study setting	Author	Study Details	Type of GP Involvement	Extent of GP Involvement
RCT Norway	Holtedahl et al. 2005[42]	Cancer site: Multiple sites Length of follow-up: Six months Sample size: GP group n = 41, hospital n = 50 Survey response rate: GP group 88%, hospital 90%	Formal involvement	Patients in the GP group received a 30-minute invited consultation with the GP and an invitation to further GP visits
RCT Denmark	Nielsen et al. 2003[46]	Cancer site: Multiple sites Length of follow-up: Six months since diagnosis Sample size: GP group n = 121, hospital n = 127 Questionnaire response rate: GP group 78%, hospital 64%	Formal involvement	Patients were encouraged to visit their GP
RCT Denmark	Bergholdt et al. 2012[36]	Cancer site: Multiple sites Length of follow-up: 14 months Sample size: GP group n = 486, hospital n = 469 Response rate: Overall response rate reported = 71%	Formal involvement	GPs were encouraged to contact the patients and facilitate the rehabilitation process
Cross-sectional study United States	Forsythe et al. 2012[133]	Cancer site: Breast and colon Sample size: PCPs n = 1,021, ONCs n = 1,130 Survey response rate: Not specified	Informal involvement	Patients attended a GP while still receiving follow-up from the specialists
Prospective longitudinal study Canada	Aubin et al. 2010[132]	Cancer site: Lung cancer Length of follow-up: 18 months Sample size: n = 395 Survey response rate: 56.8%	Informal involvement	Patients attended a GP while still receiving follow-up from the specialists
Retrospective cohort study Netherlands	Roorda et al. 2012[134]	Cancer site: Breast Sample size: Pts n = 185, Refgrp n = 585	Not specified	GPs were 'informally' involved in the follow-up care of cancer patients
Cross-sectional study United States	Haggstrom et al. 2009[50]	Cancer type: Colorectal cancer Sample size: n = 303 Survey response rate: Not specified	Informal involvement	Patients attended a GP while still receiving follow-up from the specialists

Note: hospital = control group, Int = intervention group (GPs involved in cancer care), Dx = diagnosis, ONC = oncologist, Pts = patients, Refgrp = reference group (women without breast cancer).

Appendix 2.4: Critical Review of RCTs Assessing GP Involvement in Cancer Care Using CONSORT

Section/Topic	Item No.	Checklist Item	Bergholdt et al. 2012[36]	Holtedahl et al. 2005[42]	Nielsen et al. 2003[46]
			Reported on page no.	Reported on page no.	Reported on page no.
Title and abstract	1a	Identified as a randomised trial in the title	1	949	263
	1b	Structured summary of trial design, methods, results and conclusions (for specific guidance, see CONSORT for abstracts)	1	949	263
Introduction					
Background and objectives	2a	Scientific background and explanation of rationale	2	949	263
	2b	Specific objectives or hypotheses	2	949	263
Methods					
Trial design	3a	Description of trial design (such as parallel or factorial), including allocation ratio	2	Not clarified	Not clarified
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not clarified		Not clarified
Participants	4a	Eligibility criteria for participants	2	950	264
	4b	Settings and locations where the data were collected	2	950	263
Interventions	5	The interventions for each group with sufficient details to allow replication, including	3	950	263–264

Section/Topic	Item No.	Checklist Item	Bergholdt et al. 2012[36]	Holtedahl et al. 2005[42]	Nielsen et al. 2003[46]
			Reported on page no.	Reported on page no.	Reported on page no.
		how and when they were actually administered			
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	4	950	264
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not clarified	Not clarified	Not clarified
Sample size	7a	How sample size was determined	4	952	264
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not clarified	Not clarified	Not clarified
Randomisation					
Sequence generation	8a	Method used to generate the random allocation sequence	4	950	265
	8b	Type of randomisation, and details of any restriction (such as blocking and block size)	4	Not clarified	265
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	4	950	265
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4	950	265

Section/Topic	Item No.	Checklist Item	Bergholdt et al. 2012[36]	Holtedahl et al. 2005[42]	Nielsen et al. 2003[46]
			Reported on page no.	Reported on page no.	Reported on page no.
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers or those assessing outcomes) and how	4	950	265
	11b	If relevant, description of the similarity of interventions	Not clarified	Not clarified	Not clarified
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	4	952	264
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	4	952	Partially clarified
Results					
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	4	951	266
	13b	For each group, losses and exclusions after randomisation, together with reasons	2	951	266
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4	Partially clarified	265
	14b	Why the trial ended or was stopped	Not applicable	Not applicable	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	4	952	265

Section/Topic	Item No.	Checklist Item	Bergholdt et al. 2012[36]	Holtedahl et al. 2005[42]	Nielsen et al. 2003[46]
			Reported on page no.	Reported on page no.	Reported on page no.
Numbers analysed	16	For each group, the number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	5–7	953–954	265, 267–270
Outcomes and estimation	17a	For each primary and secondary outcome, the results for each group and the estimated effect size and its precision (such as 95% confidence interval)	5–7	953–954	267–270
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	Not applicable	Not clarified
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	5–7	953–954	Partially clarified
Harms	19	All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms)	Not clarified	Not clarified	Not clarified
Discussion					
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision and (if relevant) multiplicity of analyses	6	955	268
Generalisability	21	Generalisability (external validity and applicability) of the trial findings	6	955	268

Section/Topic	Item No.	Checklist Item	Bergholdt et al. 2012[36]	Holtedahl et al. 2005[42]	Nielsen et al. 2003[46]
			Reported on page no.	Reported on page no.	Reported on page no.
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	6-Aug	955	267–270
Other information					
Registration	23	Registration number and name of trial registry	Not clarified	Not clarified	Not clarified
Protocol	24	Where the full trial protocol can be accessed, if available	Not clarified	Not clarified	Not clarified
Funding	25	Sources of funding and other support (such as supply of drugs) and role of funders	8	955	271

Appendix 2.5: Critical Review of Observational Studies Assessing GP Involvement in Cancer Care Using STROBE

Item	Descriptor	Sisler et al. 2012 [129]	Roorda et al. 2012 [134]	Haggstrom et al. 2009[50]	Aubin et al. 2010 [132]	Forsythe et al. 2012[133]	Earle et al. 2014[233]	Ludstrom et al. 2011[135]	Snyder et al. 2008 [234]	Mahboubi et al. 2006[235]
Title and abstract	a. Indicate the study's design with a commonly used term in the title or abstract	Y	Y	N	Y	Y	N	Y	Y	Y
	b. In the abstract, provide an informative and balanced summary of what was done and what was found	Y	Y	Y	Y	Y	Y	Y	Y	Y
Introduction										
Background	Explain the scientific background and rationale for the investigation being reported	Y	Y	Y	Y	Y	Y	Y	Y	Y
Objectives	State specific objectives, including any pre-specified hypotheses	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Study design mentioned earlier in the paper	Y	Y	Y	Y	Y	Y	Y	Y	Y
Study design	Present key elements of the study design early in the paper	N	N	N	Y	Y	Y	Y	Y	Y
Setting	Describe the setting, locations and relevant dates, including periods of recruitment, exposure, follow-up and data collection	Y	Y	Y	Y	Y	Y	Y	Y	Y

Item	Descriptor	Sisler et al. 2012 [129]	Roorda et al. 2012 [134]	Haggstrom et al. 2009[50]	Aubin et al. 2010 [132]	Forsythe et al. 2012[133]	Earle et al. 2014[233]	Ludstrom et al. 2011[135]	Snyder et al. 2008 [234]	Mahboubi et al. 2006[235]
Participants	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Y	Y	Y	Y	Y	Y	Y	Y	Y
Variables	Clearly define all outcomes, exposures, predictors, potential confounders and effect modifiers. Give diagnostic criteria, if applicable	N	N	Y	Y	Y	Y	Y	Y	Y
Data sources/measurement	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there was more than one group	Y	N	Y	N	Y	Y	Y	Y	Y
Bias	Describe any efforts to address potential sources of bias	Y	Y	N	N	Y	Y	Y	Y	N
Quantitative variables	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Y	Y	Y	Y	Y	Y	Y	Y	Y
Sample size	Explain how the study size was reached	Y	N	N	N	Y	N	N	N	Y
Statistical methods	(a) Describe all statistical methods, including those	Y	Y	Y	N	Y	Y	Y	Y	Y

Item	Descriptor	Sisler et al. 2012 [129]	Roorda et al. 2012 [134]	Haggstrom et al. 2009[50]	Aubin et al. 2010 [132]	Forsythe et al. 2012[133]	Earle et al. 2014[233]	Ludstrom et al. 2011[135]	Snyder et al. 2008 [234]	Mahboubi et al. 2006[235]
	used to control for confounding									
	(b) Describe any methods used to examine subgroups and interactions	Y	Y	Y	N	Y	Y	Y	Y	Y
	(c) Explain how missing data were addressed	N	N	N	N	N/A	N/A	N	N/A	Y
	(d) Cohort study: If applicable, explain how loss to follow-up was addressed	N/A	N/A	N/A	N	Y	N/A	N/A	N/A	N/A
	Case-control study: If applicable, explain how matching of cases and controls was addressed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Cross-sectional study: If applicable, describe analytical methods taking account of sampling strategy	Y	N/A	N	N/A	Y	N/A	Y	N/A	N/A
	(e) Describe any sensitivity analyses	Y	N	N	N	N	N	N	Y	N/A
Results										
Participants	(a) Report numbers of individuals at each stage of study—e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Y	Y	Y	Y	Y	Y	Y	Y	Y

Item	Descriptor	Sisler et al. 2012 [129]	Roorda et al. 2012 [134]	Haggstrom et al. 2009[50]	Aubin et al. 2010 [132]	Forsythe et al. 2012[133]	Earle et al. 2014[233]	Ludstrom et al. 2011[135]	Snyder et al. 2008 [234]	Mahboubi et al. 2006[235]
	(b) Give reasons for non-participation at each stage	Y	Y	N	Y	Y	N/A	Y	N/A	N/A
	(c) Consider using a flow diagram	N	Y	Y	Y	N	N/A	Y	N	N
Descriptive	(a) Give characteristics of study participants (e.g. demographic, clinical and social) and information on exposures and potential confounders	Y	Y	Y	Y	Y	y	Y	Y	Y
Data	(b) Indicate number of participants with missing data for each variable of interest	Y	N	N	N	Y	N	N	N	Y
	(c) Cohort study: Summarise follow-up time (e.g. average and total amount)	N/A	N/A	N/A	Y	N/A	Y	N/A	Y	Y
Outcome data	Cohort study: Report numbers of outcome events or summary measures over time	N/A	N/A	N/A	Y	N/A	Y	N/A	Y	Y
	Case-control study: Report numbers in each exposure category, or summary measures of exposure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Cross-sectional study: Report numbers of outcome events or summary measures	Y	Y	Y	N/A	Y	N/A	Y	N/A	N/A
Main results	a) Give unadjusted estimates and, if applicable, confounder-	Y	Y	Y	Y	Y	Y	Y	Y	Y

Item	Descriptor	Sisler et al. 2012 [129]	Roorda et al. 2012 [134]	Haggstrom et al. 2009[50]	Aubin et al. 2010 [132]	Forsythe et al. 2012[133]	Earle et al. 2014[233]	Ludstrom et al. 2011[135]	Snyder et al. 2008 [234]	Mahboubi et al. 2006[235]
	adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included									
	(b) Report category boundaries when continuous variables were categorised	Y	Y	Y	Y	Y	N/A	Y	Y	Y
	(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A	N/A	N	N	Y	Y	Y	Y	Y
Other analyses	Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses	Y	Y	N	Y	Y	Y	Y	Y	Y
Discussion										
Key results	Summarise key results with reference to study objectives	Y	Y	Y	Y	Y	Y	Y	Y	Y
Limitations	Discuss limitations of the study, taking into account sources of potential bias or imprecision	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Discuss direction and magnitude of any potential bias						Y	Y	Y	Y
Interpretation	Give a cautious overall interpretation of results	Y	Y	Y	Y	Y	Y	Y	Y	Y

Item	Descriptor	Sisler et al. 2012 [129]	Roorda et al. 2012 [134]	Haggstrom et al. 2009[50]	Aubin et al. 2010 [132]	Forsythe et al. 2012[133]	Earle et al. 2014[233]	Ludstrom et al. 2011[135]	Snyder et al. 2008 [234]	Mahboubi et al. 2006[235]
	considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence									
Generalisability	Discuss the generalisability (external validity) of the study results	Y	Y	N	Y	Y	Y	Y	Y	Y
Other information										
Funding	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article was based	N	Y	Y	Y	Y	N	Y	Y	Y
Total		**27/31**	**24/31**	**21/33**	**24/34**	**31/33**	**24/30**	**30/34**	**30/33**	**30/32**

Key: Y = yes, N = no, N/A = not applicable.

Appendix 2.6: Critical Review of Qualitative Studies Assessing GP Involvement in Cancer Care Using Walsh and Downie Criteria

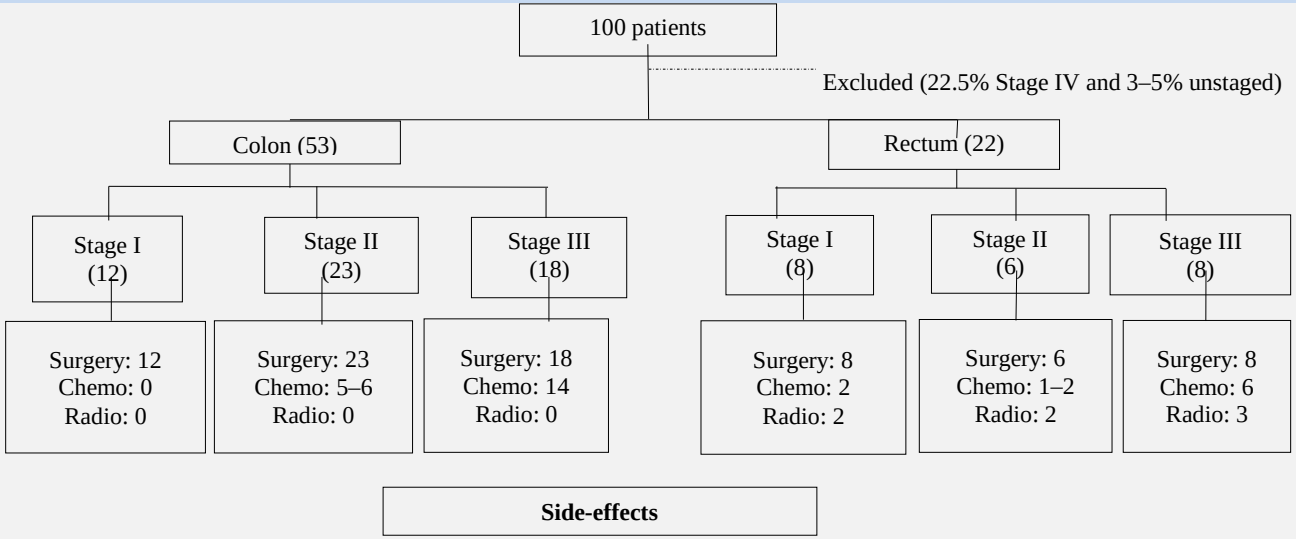
Stages	Essential Criteria	Specific Prompts	Hudson et al. 2012[137]	Hall et al. 2011[41]	Anvik et al. 2006[140]
Scope and purpose	Clear statement of and rationale for research questions, aims and purposes	Clarity of focus demonstrated	Y	Y	Y
		Explicit purpose given, such as descriptive/explanatory intent, theory building and hypothesis testing	Y	Y	Y
		Link between research and existing knowledge demonstrated	Y	Y	Y
	Study thoroughly contextualised by existing literature	Evidence of systematic approach to literature review, location of literature to contextualise the findings, or both	Y	Y	Y
Design	Method/design apparent and consistent with research intent	Rationale given for use of qualitative design	Y	Y	Y
		Discussion of why particular method chosen is most appropriate, sensitive and relevant to research questions and aims	Y	Y	Y
		Discussion of epistemological/ontological grounding	Y	Y	Y
	Data collection strategy apparent and appropriate	Were data collection methods appropriate for the type of data required and the specific qualitative method?	Y	Y	Y
		Were they likely to capture the complexity/diversity of experience and illuminate context in sufficient detail?	Y	Y	Y
		Was triangulation of data sources used, if appropriate?	N/A	Y	Y
Sampling strategy	Sample and sampling method appropriate	Selection criteria detailed, and description of how sampling was undertaken	Y	Y	Y
		Justification for sampling strategy given	N	Y	N
		Thickness of description likely to be achieved from sampling	Y	Y	Y
		Any disparity between planned and actual sample explained	Y	Y	N

Stages	Essential Criteria	Specific Prompts	Hudson et al. 2012[137]	Hall et al. 2011[41]	Anvik et al. 2006[140]
Analysis	Analytic approach appropriate	Approach made explicit (e.g. thematic distillation, constant comparative method, grounded theory)	Y	Y	Y
		Was it appropriate for the qualitative method chosen?	Y	Y	Y
		Were data managed by software package or by hand, and why?	Y	Y	Y
		Discussion of how coding systems/conceptual frameworks evolved	Y	Y	Y
		How was context of data retained during analysis?	Y	Y	Y
		Evidence that the subjective meanings of participants were portrayed	N	Y	Y
		Evidence of more than one researcher involved in stages, if appropriate to epistemological/theoretical stance	Y	Y	Y
		Did research participants have any involvement in analysis (e.g. member checking)?	Y	Y	Y
		Evidence provided that data reached saturation, or discussion and rationale if it did not	Y	Y	Y
		Evidence that deviant data were sought, or discussion and rationale if they were not	N	N	N
Interpretation	Context described and taken account of in interpretation	Description of social/physical and interpersonal contexts of data collection	Y	Y	Y
	Clear audit trail given	Evidence that researcher spent time 'dwelling with the data', interrogating it for competing or alternative explanations of phenomena	Y	Y	Y
		Sufficient discussion of research processes so that others can follow the 'decision trail'	Y	Y	Y
	Data used to support interpretation	Extensive use of field notes entries/verbatim interview quotations in discussion of findings	Y	Y	Y

Stages	Essential Criteria	Specific Prompts	Hudson et al. 2012[137]	Hall et al. 2011[41]	Anvik et al. 2006[140]
		Clear exposition of how interpretation led to conclusions	Y	Y	Y
Reflexivity	Researcher reflexivity demonstrated	Discussion of relationship between researcher and participants during fieldwork	Y	Y	Y
		Demonstration of researcher's influence on stages of research process	Y	Y	Y
		Evidence of self-awareness/insight	Y	Y	Y
		Documentation of effects of the research on researcher	N	N	N
		Evidence of how problems/complications were managed	Y	Y	Y
Ethical dimensions	Demonstration of sensitivity to ethical concerns	Ethical committee approval granted	Y	Y	Y
		Clear commitment to integrity, honesty, transparency, equality and mutual respect in relationships with participants	Y	Y	Y
		Evidence of fair dealing with all research participants	Y	Y	Y
		Record of dilemmas and how they were resolved in relation to ethical issues	Y	Y	Y
		Documentation of how autonomy, consent, confidentiality and anonymity were managed	Y	Y	Y
Relevance and transferability	Relevance and transferability evident	Sufficient evidence for typicality specificity to be assessed	Y	Y	Y
		Analysis interwoven with existing theories and other relevant explanatory literature drawn from similar settings and studies	Y	Y	Y
		Discussion of how explanatory propositions/emergent theory may fit other contexts	Y	Y	Y
		Limitations/weaknesses of study clearly outlined	Y	Y	Y
		Clearly resonates with other knowledge and experience	Y	Y	Y
		Results/conclusions obviously supported by evidence	Y	Y	Y

Stages	Essential Criteria	Specific Prompts	Hudson et al. 2012[137]	Hall et al. 2011[41]	Anvik et al. 2006[140]
		Interpretation plausible and 'makes sense'	Y	Y	Y
		Provides new insights and increases understanding	Y	Y	Y
		Significance for current policy and practice outlined	Y	Y	Y
		Assessment of value/empowerment for participants	Y	Y	Y
		Outlines further directions for investigation	Y	Y	Y
		Comment on whether aims/purposes of research were achieved	Y	Y	Y
Total			**49/50**	**49/51**	**47/51**

Appendix 3.1: Distribution of Side-effects Based on a Cohort of 100 Patients



Physical

Diarrhoea: n = 10 (13–14%[1-4])

Constipation: n = 5 (7%[1])

BO urgency: n = 15 (20–22%[2, 3])

Faecal incontinence: n = 10 (14–16%[2, 3])

Urine incontinence: n = 9 (38%[1])

Urine retention: n = 7 (31%[1])

Physical

Weight loss n = 1–6 (5–55%[1])

Peripheral-neuropathy: n = 4 (12%[10])

Nausea/vomiting: n = 1–6 (5–55%[1])

Fatigue: n = 17 (23%[1])

Pain and cramping: n = 5 (7%[1])

Psychological

*Negative body image: n = 6 (25%)

*Sexual dysfunction: n = 6 (26%[1, 5, 6])

Depression: n = 19 (25%[7])

Fear of recurrence: n = 50 (67–68%[6-8])

Anxiety: n = 5 (7%[7])

Poor sleep pattern: n = 36 (48%[9])

Social

Activity limitation: n = 11 (15%[3])

Financial difficulties: n = 35 (48.8%[11])

Appendix 3.2: Panellists' Score Sheet

Please rate the following questions based on the level of importance.

e.g. Extremely unimportant 1 ☐ 2 ☐ 3 ☒ 4 ☐ 5 ☐ Extremely important

RE: PATIENTS TREATED FOR LOWER BOWEL CANCER

The following issues/problems have been identified from the literature as being important side-effects in the years after active treatment (usually more than one year). Such problems or issues may be raised by patients during their follow-up appointments.

From your experience, please indicate how important each issue is for patients to raise with their doctor.

1. Diarrhoea (loose, watery bowel motions)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
2. Inability to defer a bowel movement for more than 15 minutes	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
3. Leakage of stool	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
4. Need to wear protective pads due to leakage of stool	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
5. Frequent bowel movements during the night (three times or more)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. Frequent bowel movements during the day (three times or more)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
7. Abdominal pain	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
8. Constipation	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
9. The need to spend money managing bowel issues	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
10. Feeling nauseous or vomiting	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
11. Poor appetite	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
12. Feeling more tired than usual (fatigued)	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
13. Pain and tingling sensations in the fingers	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
14. Difficulties starting to pass urine ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
15. Inability to control leakage of urine ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Curtin University

Please rate the following questions based on the level of importance.

e.g. Extremely unimportant 1 ☐ 2 ☐ 3 ☒ 4 ☐ 5 ☐ Extremely important

16. Need to wear protective pads due to leakage of urine ☐	1	☐	2	☐	3	☐	4	☐	5
17. (**For women**) ☐	1	☐	2	☐	3	☐	4	☐	5
18. (**For men**) Difficulties getting or maintaining an ☐	1	☐	2	☐	3	☐	4	☐	5
19. Difficulty sleeping ☐	1	☐	2	☐	3	☐	4	☐	5
20. Feeling anxious ☐	1	☐	2	☐	3	☐	4	☐	5
21. Feeling depressed ☐	1	☐	2	☐	3	☐	4	☐	5
22. Unintentional weight loss ☐	1	☐	2	☐	3	☐	4	☐	5
23. Negative body image ☐	1	☐	2	☐	3	☐	4	☐	5
24. Fear of recurrence ☐	1	☐	2	☐	3	☐	4	☐	5
25. Need for dietary advice ☐	1	☐	2	☐	3	☐	4	☐	5
26. Financial difficulties ☐	1	☐	2	☐	3	☐	4	☐	5
27. Difficulties driving a car ☐	1	☐	2	☐	3	☐	4	☐	5
28. Inability to do things around the house ☐ (gardening, cleaning, working in the shed)	1	☐	2	☐	3	☐	4	☐	5
29. Inability to go shopping ☐	1	☐	2	☐	3	☐	4	☐	5

Other symptoms you think are extremely important (5 ☒)and have been left out:

1. Enter symptom here
2. Enter symptom here
3. Enter symptom here
4. Enter symptom here
5. Enter symptom here

Thank you for your participation in this research project.

Appendix 3.3: Participant Information Sheet and Consent Forms

PARTICIPANT INFORMATION SHEET

Colorectal Cancer Follow-up: An Intervention to Support Patients Following Treatment

Investigators: Ms Irene Ngune, Professor Moyez Jiwa, Professor Alexander McManus, Professor Jeff Hughes and Dr Rupert Hodder.

Please take time to read the following information carefully and to discuss it with your family, friends and general practitioner, if you wish. If any part of the information is not clear to you, or if you would like more information, do not hesitate to ask us to explain it more fully. Make certain you do this before you sign the consent form to participate in this study.

Who is funding this study?
Primary Health Care Research Evaluation and Development

Contact people:
If you have any questions about the study, you can contact:

Irene Ngune: telephone—08 9266 9213 or email—I.ngune@curtin.edu.au

Decision to participate:
Your decision to participate in this study is *voluntary*—that is, you may decide to be in this study or not take part in it at all. If do you decide to participate, you are able to change your mind at any time during the study. However, before you make any decision, it is important that you understand why this study is being done and what it will involve, including your rights and responsibilities. You will be given a copy of this Participant Information Sheet and Consent Form to keep for your personal record.

Any decision you make *will not* affect your regular medical care or any benefit to which you would otherwise be entitled.

The Participant Information Sheet explains the study and includes details such as:

- why this study might be suitable for you
- possible benefits and risks of the study
- what your rights and responsibilities are if you agree to participate.

What is the purpose of this study?
You are invited to participate in a study that assesses health issues that may come up after completing colorectal cancer treatment. A self-assessment form will be developed that will assist patients to be able to identify symptoms or issues they may experience during follow-up, keep a record of these issues/symptoms, and use the form as a guide to consult their clinician. We wish to identify the benefits patients may receive after being provided with this additional support (self-assessment tool) during follow-up.

Why is this study suitable to me?

You are eligible to participate in this study because you have completed colorectal cancer treatment and are receiving follow-up care.

How long will I be in this study?
If you agree to participate, you will be enrolled for a period of six months. This study does not prevent you from seeking healthcare or attending medical appointments you may have with your clinician/specialist.

What will happen if I decide to be in this study?
If you agree to participate, you may be given an assessment tool that you will use to record any issues you experience while receiving follow-up, and you can use it when you visit your general practitioner (GP).

Also, at the beginning of the study and at several points within the six months, you will be sent surveys and/or you will be telephoned by a researcher to ask questions about your health. All your details will remain confidential and will only be known by the researcher.

Your GP will also be asked about symptoms you may have reported to him or her and the investigations that your GP may have done over the six months.

Are there any reasons I should not be in this study?
You should not participate in this study if you have not completed treatment for colorectal cancer. Eligible participants will be those who are receiving or have completed follow-up with their clinician/specialist.

What are the costs to me?
We do not anticipate there will be any costs associated with this study.

What are the possible benefits of taking part, to me and to the wider community?
This study will enable us to determine whether colorectal cancer patients and their clinicians would benefit from using this self-assessment form during consultation. Your involvement may benefit you, but it may also be of benefit to other patients like you who will use the form.

How will my safety be ensured?
No harm is expected to result from your involvement in this study. The surveys may contain questions that are personal or private. If for any reason you find these upsetting, you may choose not to answer the question or you may choose to speak with your doctor. If for any reason you choose to withdraw from the study, you are free to do so without having to give a reason.

What are my alternatives if I do not want to participate in this study?
If for any reason you choose not to participate in this study, you are free to do so without giving a reason to the researcher. This will not affect your treatment or medical appointments in any way.

What are the possible side-effects, risks and discomforts of taking part?
The researchers will need to collect personal data about you, which may be sensitive. Examples of such data include your name, contact details, date of birth and relevant health information.

However, any personal or health information will be kept private and confidential. It will be stored securely, and only authorised people who understand that it must be kept confidential will have access to it. Your study details will be given a number so that your identity will not be apparent. The data collected will be stored securely, then archived and destroyed according to the Sir Charles Gardner Hospital and Curtin University policies.

All electronic records will be identified by a unique study number. The database will be protected from unauthorised access and will not be available to anyone other than the researchers involved in this study. The results of the research will be made available to other health professionals through medical journals or meetings, but you will not be identifiable.

What if new information comes along during the study?

We do not anticipate the study will have any new information that will affect your treatment. However, if for any reason new information becomes available that may affect whether you wish to continue with the study, you may be asked to sign a new consent form.

Could the study be stopped early?
Sometimes a study may need to be stopped. The reasons a study may end early include safety concerns for the participants, because the researcher chooses to stop the study early, or for other reasons. If this does occur, you will be notified of the reasons, if known.

What happens at the end of the study?
At the end of the study, the participants will retain a copy of the self-assessment tool and use it if they wish. Participants will continue with their usual follow-up care as scheduled by their clinicians.

Will my taking part in this study be kept confidential?
The researchers will need to collect personal data about you, which may be sensitive. Examples of such data include your name, contact details, date of birth and relevant health information.

However, any personal or health information will be kept private and confidential. It will be stored securely and only authorised people who understand that it must be kept confidential will have access to it. Your study details will be given a number so that your identity will not be apparent. All electronic records will be identified by a unique study number. The database will be protected from unauthorised access and will not be available to anyone other than the researchers involved in this study. The results of the research will be made available to other health professionals through medical journals or meetings, but you will not be identifiable.

How can I find out the results of this study?
In due course, the researchers will send you information about the results of the study. The results of the study will also be published in peer-reviewed journals and presented at national and international conferences. You may find out about the study results by reading these articles or by contacting the researcher directly.

Who has reviewed this study?
The Sir Charles Gardner Group and Curtin University Human Research Ethics Committees have reviewed this study and given approval for the conduct of this research study. In doing so, this research conforms to the principles established by the National Statement on Ethical Conduct in Human Research, and abides by the Good Clinical Practice Guidelines.

In the case of a medical emergency, please call 000.

CONSENT FORM

Colorectal Cancer Follow-up: An Intervention to Support Patients Following Treatment

Investigators: Ms Irene Ngune, Professor Moyez Jiwa, Professor Alexander McManus, Professor Jeff Hughes and Dr Rupert Hodder.

Participant Name:

Date of Birth: _____

Name of your GP:

Name and practice address of your GP:

NOTE: If you are still unclear about anything you have read in the Participant Information Sheet and Consent Form, please speak to your doctor before signing this Consent Form.

1. I have been given information, both verbally and in writing, about this study and, having had time to consider it, am now able to make an informed decision to participate.

2. I have been told about the potential benefits and known risks of taking part in this study and I understand what this means to me.

3. I was given the opportunity to have a family member or friend with me when this study was being explained to me. I have been able to ask questions and have had all my questions answered.

4. I know that I do not have to take part in this study, and that my decision to take part is voluntary. I understand that I can withdraw from this study at any time without this decision affecting my medical care.

5. I understand that participating in this study does not affect any right to compensation, which I may have under statute or common law.

6. I accept that by taking part in this research, any information obtained about me during the study may be published, provided that my name and other identifying information are not used.

Name of Participant	Signature of Participant	Date

Irene Ngune

Name of Researcher	Signature of Researcher	Date

The Sir Charles Gairdner Group Human Research Ethics Committee has granted approval for the conduct of this study. If you have any concerns about the ethics or code of practice of the study, please contact the Executive Officer of the Sir Charles Gairdner Group Human Research Ethics Committee on (08) 9346 2999.

This study has also been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 42/2012). If needed, the verification of approval can be obtained by writing to the Curtin University Human Ethics Committee (c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845), by telephoning 92662784 or by emailing hrec@curtin.edu.au.

Appendix 3.4: Self-assessment Tool for Patients (SATp)

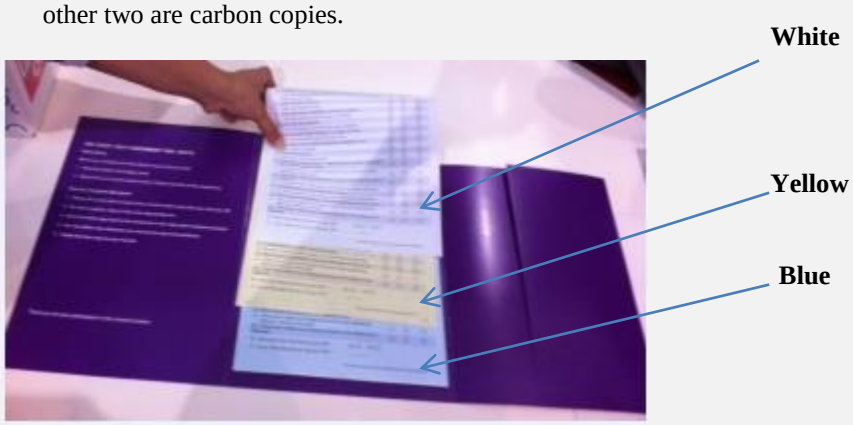
These questions relate to issues that you might experience as a result of your colorectal cancer treatment. Please tick the answer that best describes your response.	Yes	No
1. I have had diarrhoea (loose watery bowel motions)		
2. I have been unable to defer a bowel movement for more than 15 minutes		
3. I have needed to wear protective pads due to leakage of stool		
4. I have had frequent bowel movements (3 or more) during the night and/or day		
5. I have had abdominal pain		
6. I have had flatulence		
7. I have spent money managing my bowel issues		
8. I have felt nauseous (sick) or vomited		
9. I have had a poor appetite		
10. I have been feeling more tired than usual (fatigued)		
11. I have had pain and/or tingling in my fingers and toes		
12. I have had difficulties starting to pass urine		
13. I have needed to wear protective pads due to leakage of urine		
14. I have had difficulty sleeping		
15. I have been anxious		
16. I have been feeling depressed		
17. I have had sexual problems (vaginal dryness for women, or ejaculation and erection problems for men)		
18. During the past month, my cancer treatment has caused me to lose weight that concerns me		
19. I have been concerned about how my body looks since having my treatment		
20. During the past month, I have been worried that my cancer will return		
21. I have needed advice about what I should be eating		
22. My cancer treatment has caused me some financial difficulties		
23. Since having my treatment, I have had difficulties driving my car		
24. Since having my treatment, I have been unable to do things around the house (gardening, cleaning, working in the shed)		
25. I have been unable to go shopping because of the effects of my treatment		
26. Have you shown this form to your GP?		
27. If yes, what date did you visit your GP? _ _/_ _/_ _		

Appendix 3.5: SATp Instruction Manual

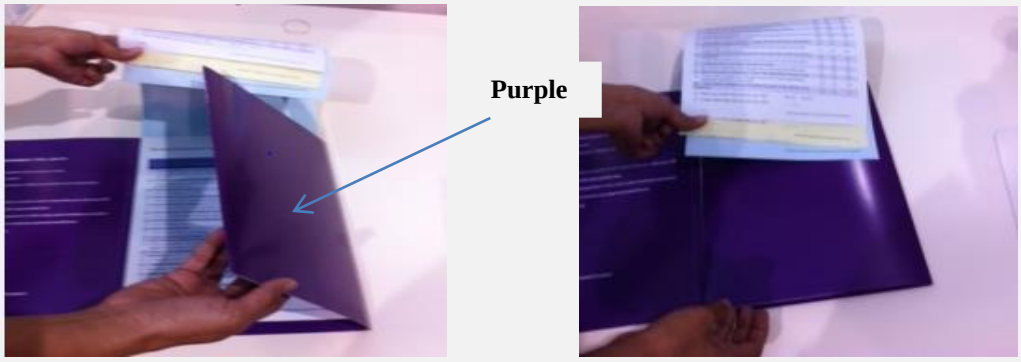
Dear Participant

Thank you for choosing to participate in this study.

1. In this booklet there are 10 sets of forms.
2. Each set contains three forms (white, yellow and blue). The white form is the original and the other two are carbon copies.



3. Before filling out the forms, please flip the first set (white, yellow and blue) over onto the purple cover (the right hand flap of the purple folder). This is to protect the set underneath.



Once you have completed the first set:

- Please send the **white copy** back to me. There is a reply-paid envelope attached.
- Please give the **yellow copy** to your GP whenever you visit him or her, even if your reason for the visit is not bowel cancer. This is to keep your GP updated of the issues you are experiencing while you are receiving follow-up. Your GP is aware that you are participating in this study.
- The **blue copy** is for your records, and you are welcome to use it during your follow-up clinic appointments at Sir Charles Gairdner Hospital.

Please fill out a set once every month and any other time before you visit your GP.

Thank you for your participation.

Colorectal Cancer Research Team

Appendix 3.6: Letter of Acceptance for Publication of the SATp Manuscript

Quality in Primary Care ~ Acceptance ~ Development of a patient-administered self-assessment tool (SATp) for follow-up of CRC patients in general practice
Susan Bowler <sbowler@lincoln.ac.uk>
Fri 17/10/2014 11:32 AM
Inbox
To: Irene Ngune <I.Ngune@curtin.edu.au>;
Cc: Niro Siriwardena <nsiriwardena@lincoln.ac.uk>;

Dear Dr Ngune,

Development of a patient-administered self-assessment tool (SATp) for follow-up of colorectal cancer patients in general practice

Thank you for submitting the above paper. I am pleased to confirm that your article has been accepted for publication in Quality in Primary Care. Please send me the contact details for your co-authors in order that I can contact them directly.

As you will know from my recent e-mail, Quality in Primary Care has been bought by OMICS and the new arrangements for publishing the journal have not yet been finalised. This is causing delays in our usual processes and we apologise for this. We aim to keep you informed of future developments but in the meantime if you have any queries, please do not hesitate to contact me.

I should like to thank and congratulate you for the work which you and your colleagues have done and look forward to receiving further articles in the future.

Best wishes,

Sue

Sue Bowler (Mrs)
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Appendix 4.1: Study 2 Author Permission Statement

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Author's Signature

09/19/2014
Date

Appendix 4.2: TPB Survey

Section A

Instructions: Please answer every question by ticking (✓) your response in the box next to the answer that best applies to your experience

OR **write your answer in the box provided** **Written response goes here**

This questionnaire is anonymous and the responses you provide will be kept confidential. Thank you for your participation. Please complete the questions below.

1. Are you male or female?
   a) Male
   b) Female
2. What is your date of birth or age in years on your last birthday? _____
3. Where do you live?
   a) Suburb
   b) Postcode
4. What is your present marital status?
   a) Never married
   b) Widowed
   c) Married
   d) Separated, but not divorced
   e) Divorced
   f) De facto partner
5. What is the highest level of formal education you have completed?
   a) Primary school
   b) Year 10 or equivalent
   c) Year 12 or equivalent
   d) Trade certificate/TAFE
   e) University /CAE (College of Advanced Education)

Which of the following best describes your current employment status? (Tick one option)

   a) Self employed
   b) Employed for wages, salary or payment in kind
   c) Engaged in home duties
   d) Student
   e) Unable to work
   f) Unemployed
   g) Retired
   h) Other (specify) _____

Section B

The following questions are about your medical care

Check-up(s) in this section refer to a visit to your general practitioner (GP), specialist or other health professional.

6. How often did you visit a GP during the last 12 months for any reason?
   ___ ___ ___ (estimate the number of times)

7. How long ago you were first diagnosed with colorectal cancer?
   _____ (month/year)

8. Since you were first diagnosed with colorectal cancer, who have you discussed it with? (Tick all that apply)
   a) GP
   b) Surgeon
   c) Specialist
   d) Other (please specify)
   _____

9. Thinking about the last 12 months, how often have you had a medical check-up for your colorectal cancer?
   a) Every week
   b) At least once a month
   c) Every two to three months
   d) Every four to six months
   e) Once during the last 12 months
   f) I did not have regular check-ups

10. When is your next check-up about your colorectal cancer?
   a) _____(month/year)
   b) I do not have a check-up scheduled

11. Do you visit a GP for any other health conditions?
   a) Yes
   b) No (if no, please go to Section C)

12. What health conditions do you have other than colorectal cancer (e.g. diabetes, high blood pressure, etc.)?

_____

Section C

The following questions ask about choices of medical care during the next six months.

Please circle the number that best describes your level of agreement with the following statements

e.g. Likely 1 2 3 4 5 Unlikely

It is important that the doctors I see have all the information about my colorectal cancer and treatment	Strongly disagree	1	2	3	4	5	Strongly agree
Attending a GP about my colorectal cancer is likely to detect problems and side-effects early	Not likely	1	2	3	4	5	Likely
Attending a GP about my colorectal cancer will reassure me	Strongly disagree	1	2	3	4	5	Strongly agree

Please circle the number that best describes your level of agreement with the following statements

e.g. Strongly disagree 1 2 3 4 5 Strongly agree

Making a routine appointment with a GP about my colorectal cancer is	Extremely difficult	1	2	3	4	5	Extremely easy
For me to travel to see a GP about my colorectal is	Extremely difficult	1	2	3	4	5	Extremely easy
It is easy for me to attend a GP about my colorectal cancer	Strongly Disagree	1	2	3	4	5	Strongly agree
It is affordable for me to attend a GP about my colorectal cancer	Strongly Disagree	1	2	3	4	5	Strongly agree

Please circle the number that best describes your level of agreement with the following statements

e.g. Strongly disagree 1 2 3 4 5 Strongly agree

My family members think I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree
My close friends think I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree
My specialist thinks I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree
My cancer care nurse at the hospital thinks I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree
Most people who are important to me think I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree

Please circle the number that best describes your level of agreement with the following statements

e.g. Strongly disagree 1 2 3 4 5 Strongly agree

In the next six months, I am likely to attend a GP	Very unlikely	1	2	3	4	5	Very likely
In the next six months, I am likely to talk about my colorectal cancer with a GP	Very unlikely	1	2	3	4	5	Very likely
In the next six months, I intend to only visit a specialist for my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree

Thank you for taking the time to complete this survey.

Appendix 4.3: TPB Questionnaire Score Sheet

Questions measuring attitudes towards attending a GP for colorectal cancer care							
It is important that the doctors I see have all the information about my colorectal cancer and treatment	Strongly disagree	1	2	3	4	5	Strongly agree
Attending a GP about my colorectal cancer is likely to detect problems and side-effects early	Not likely	1	2	3	4	5	Likely
Attending a GP about my colorectal cancer will reassure me	Strongly disagree	1	2	3	4	5	Strongly agree

Scoring: Record negatively worded end points ('bad' and 'unpleasant [for me]') to reflect lower scores. E.g. bad = 1 and good = 5, while the middle score = 3. Calculate the mean of the score to give an overall attitude score.

Questions measuring intentions of attending a GP for CRC care							
In the next six months, I am likely to attend a GP	Very unlikely	1	2	3	4	5	Very likely
In the next six months, I am likely to talk about my colorectal cancer with a GP	Very unlikely	1	2	3	4	5	Very likely
In the next six months, I intend to only visit a specialist for my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree

Scoring: Calculate the mean of the three intention scores.

Questions measuring PCB							
Making a routine appointment with a GP about my colorectal cancer is	Extremely difficult	1	2	3	4	5	Extremely easy
For me to travel to see a GP about my colorectal cancer is	Extremely difficult	1	2	3	4	5	Extremely easy
It is easy for me to attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree
It is affordable for me to attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree

Scoring: Record negatively worded end points to reflect lower scores. E.g. bad = 1 and good = 5, while the middle score = 3. Calculate the mean of the score to give an overall PCB score.

Questions measuring PCB							
My family members think I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree
My close friends think I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree
My specialist thinks I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree
My cancer care nurse at the hospital thinks I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree
Most people who are important to me think I should attend a GP about my colorectal cancer	Strongly disagree	1	2	3	4	5	Strongly agree

Scoring: Recode negatively worded endpoints on the right, so that high scores consistently reflect greater social pressure to do the target behaviour. Calculate the mean of the item scores to give an overall subjective norm.

Appendix 5.1: Clinical Records Data Extraction Pro-forma

Item	Details	Coding
Patient study ID	_____	
Name of the GP	_____	
Date visited GP	_ _ /_ _ /_ _ _ _(DD/MM/YYYY)	
If SATp presented	Yes	☐[1]
	No	☐[2]
	Not indicated	☐[3]
Type of treatment offered	Referral	☐[1]
	investigation	☐[2]
	Prescription	☐[3]
Referred to	Specialist	☐[1]
	AHW	☐[2]
	Other	☐[3]
Investigations offered	Radiological	☐[1]
	Laboratory	☐[2]
	Other	☐[3]
Prescription offered	Analgesics	☐[1]
	Antibiotics	☐[2]
	Aperients	☐[3]
	Bulk forming agents	☐[4]
	Mood stabilisers	☐[5]
	Sedatives	☐[6]
	Other	☐[7]
If health advice offered	Yes	☐[1]
	No	☐[2]

Appendix 6.1: Example of the Video Vignettes Used (Multimedia File)

Appendix 6.2: Details of Patients Presented in the Video Vignettes

Details of patients presented in the video vignettes

Case 1: 'James'—58 years of age, married and works as a plumber. Has high blood pressure, but now stable. Diagnosed with bowel cancer (splenic flexure mucinous adenocarcinoma, no metastases in 21 lymph nodes, pT4b, N0, M0) 18 months ago and completed treatment 12 months ago (treatment offered—left hemi-colectomy, chemotherapy [Flurouracil + Leucovorin + Oxaliplatin FOLFOX]).

Presents with pain and tingling sensation in his fingertips and toes that has markedly interfered with his work. He complains of having trouble grasping items with his fingers. On examination, there is no jaundice, anaemia, cyanosis, oedema or lymphadenopathy. Neuro examination—normal; upper limbs sensation—moderately on light touch; reduced from 5 cm below elbow; reflex—absent wrist, elbow +; temp—reduced from 5 cm below elbow; position sense—abnormal; coordination—poor fine motor movements, unable to unbutton buttons.

Diagnosis: Chemotherapy-induced peripheral neuropathy.

Case 2: 'David'—60 years of age, maintenance worker at a school, previously divorce and in a new relationship for the last six months. Presented with erectile dysfunction that is affecting his relationship. He was aware such a problem would occur following surgery. His urine stream is normal. He was diagnosed with rectal cancer (mid to lower rectal mass, T3, N2, M0) and completed treatment 12 months ago (treatment offered—anterior resection, ostomy, radiotherapy long course [5/52]). He has no family history of diabetes. Random blood sugars—normal; full blood count—normal; and urea/electrolyte/creatinine—normal. Recent carcinoembryonic antigen—3 ng/ml and CT scan abdomen—normal. On examination, normal: perianal reflexes intact. No jaundice, anaemia, cyanosis, oedema or lymphadenopathy. Vital signs are within normal ranges.

Diagnosis: Erectile dysfunction secondary to lower anterior resection.

Case 3: 'Margaret'—45 years of age, peri-menopausal and has been on hormonal replacement therapy. Diagnosed with rectal cancer (low rectal mass rT3,N0, M0) two years ago and completed treatment about 18 months ago (treatment offered—low anterior resection with ostomy). Generally feeling well, but finds it difficult to cope with urinary urgency and incontinence.

Recent follow-up investigations: Pap smear—normal; thyroid function tests—normal; liver function tests—normal; Vitamin D—normal; recent carcinoembryonic antigen—3 ng/ml; CT scan abdomen—normal. No evidence of urinary tract infection. On examination, no jaundice, anaemia, cyanosis, oedema or lymphadenopathy. No abdominal tenderness; small uterus—no mass or tenderness; no per vaginal bleeding; mucosa appears normal; no punch tenderness over the kidneys. However, pelvic floor is weak.

Diagnosis: Urinary dysfunction secondary to lower anterior resection/radiation.

Case 4: 'Doreen'—54 years of age. Over the past two months, she has been feeling nauseous and sick and having lower back pain (waking her at night) and weight loss that concerns her. She was diagnosed with sgmoid adenocarcinoma T2N1m0 2.5 years ago and completed treatment two years ago (laparoscopic anterior resection and neo-adjuvant therapy). Six months ago, carcinoembryonic antigen levels—11 ng/ml and CT scan of pelvis/abdomen—small area of low attenuation near the left lateral margin of the suture line fluid collection. PET—no evidence of distant metastatic disease; CXR—clear; pap smear and liver function tests—normal. On examination, there is mild lower abdominal distension; tenderness of lower abdomen (diffuse non-specific); bowel sound +++; per rectal examination—red blood and stool on glove.

Diagnosis: Tumour recurrence.

Details of patients presented in the video vignettes

Case 5: 'Joan'—68 years of age, retired nurse. She has noninsulin-dependent diabetes mellitus, but blood sugars are under control. She has been on Metformin 500mg BD for her diabetes for many years. She can no longer take her dog for a walk. She is easily exhausted. She completed treatment for colon cancer (caecal cancer T3N0M0) one year ago, but has been feeling tired most of the time. Treatment offered: laparoscopic right hemi-colectomy; adjuvant chemotherapy (Flouroracil + leucovorin—six months). Recent carcinoembryonic antigen levels—normal; recent HbA1c 5.4—5.6%; pap smear—normal; thyroid function tests—normal; liver function tests—normal; Vitamin D—normal; mammogram—normal; ophthalmologist review—normal. On examination, there is good eye contact and emotional response is congruent.

Diagnosis: Chemotherapy-induced fatigue.

Case 6: 'Kerry'—77 years of age, retired. She is asthmatic, but the asthma is under control. She was treated for upper rectal cancer T3, N1, M0 one year ago. Her bowels have not settled since she completed the treatment—she has been experiencing diarrhoea, which has significantly affected her social life. Treatment offered: pre-operative chemo/radiotherapy 5/52 and post-operation adjuvant chemotherapy. Recent carcinoembryonic antigen—3 ng/ml and CT scan abdomen—normal. Pap smear, thyroid function tests, liver function tests, Vitamin B levels, full blood count, and urea/electrolyte/creatinine levels—normal. On examination, there is no evidence of jaundice, anaemia, cyanosis, oedema, lymphadenopathy or dehydration. Per rectal examination reveals watery stool and no blood.

Diagnosis: Chronic radiation proctitis.

Appendix 6.3: Questionnaire GP Video Vignette Study

Internet-based GP Questionnaire

Welcome to the Colorectal Cancer Study and thank you for your interest in participating. Your involvement is important in improving the management of colorectal cancer patients who have completed treatment. We hope you will enjoy taking part in this unique method for testing innovations in general practice.

Before proceeding, you are required to read the participant information (on the next page) about the study, and give consent to participate**.**

If you need further information about this study, please contact Irene on 92669213 or chiriestudies@curtin.edu.au.

Colorectal Cancer Study
Chief investigators: Irene Ngune and Professor Moyez Jiwa
Co-investigators: Professor Alexandra Mc Manus, Professor Jeff Hughes and Professor Rupert Hodder

Instructions for Participating

Participant Information Sheet

You have been asked to volunteer for a research study that aims to explore the approach to managing colorectal cancer patients who have completed treatment.

Participant Eligibility

You are eligible to participate if you are a general practitioner currently working in Australia.

Study Procedure

You will be invited to view six simulated (1.5 minutes each) standardised consultations that portray patients presenting to the GP with complications associated with colorectal cancer treatment.

You will be asked to make a decision about the management of each patient and to submit details of your decision at the time of viewing the video.

Number of Phases in this Study

This study has only one phase

Payment for Participation

To compensate for the time required to review the case scenarios and complete the associated tasks, a reimbursement of $50 will be awarded to you upon completion of the study.

Privacy and Confidentiality

We believe it is extremely important to keep your personal information confidential. Any information you provide will be kept strictly confidential.

The information provided will be used for the purpose of this project only and individual results will not be reported. No practice or doctors names will be mentioned.

Internet-based GP Questionnaire

Voluntary Participation

Participation in this study is voluntary. You may decline to take part or withdraw from this study at any time.

Risks, Benefits and Research Outcomes

There are no risks associated with your participation and any information gained from you will be treated as confidential.

This study intends to optimise primary care management of issues associated with colorectal cancer treatment.

Investigators:

Irene Ngune: I.ngune@curtin.edu.au

Professor Moyez Jiwa: m.jiwa@curtin.edu.au

Professor Alexandra McManus: A.Mcmanus@curtin.edu.au

Associate Professor Rupert Hodder: Rupert.hodder@health.wa.gov.au

This study has been approved by the Curtin University Human Research Ethics Committee (study no. HR42 2012). The committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of this approval can be obtained by writing to the Curtin University Human Ethics Committee (c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845), by telephoning (08) 9266 2784 or by emailing hrec@curtin.edu.au.

Participant consent

You have been asked to volunteer for a research study that aims to explore the approach to management of colorectal cancer patients who have completed treatment.

Please note: It is important that we are able to contact you by email, so please ensure these details are complete and correct.

Click to write the question text

Surname First Name Email address
Telephone Number

By completing the consent form below you certify that you:

□ Are a general practitioner practising in Australia.
□ Have read the Participant Information Sheet and have had any questions answered to your satisfaction by the researcher.
□ Have been informed of the benefits and risks associated with this research study.
□ Understand that you are free to withdraw from the study at any time, for any reason and without prejudice.
□ Agree to take part in this research study, and for the data obtained to be published, provided your name or other identifying information is not used.

Internet-based GP Questionnaire

If you are unclear about anything you have read in the Participant Information Sheet or this Consent Form, please speak to the researcher before signing this Consent Form.

Yes, I agree with the points above and consent to participate in this study

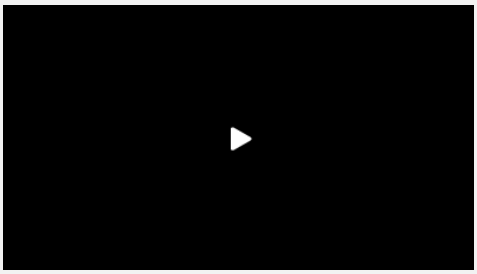
No, I have decided not to participate

This study has been approved by the Curtin University Human Research Ethics Committee (Approval study no. HR42 2012). The committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, the verification of approval can be obtained by writing to the Curtin University Human Ethics Committee (c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845), by telephoning (08) 9266 2784 or by emailing hrec@curtin.edu.au.

Video Check

The study requires you to view videos of simulated consultations. Play the test video below to ensure you can see and hear video on this website. If the video does not play, review the video troubleshooting instructions (below) for further support.

Adobe Flash plugin version 9.0.115 or later required for video playback.



Video troubleshooting steps

Download and install the Adobe Flash player
The latest Adobe Flash player for your web browser can be downloaded from the Adobe website (free download). Once you have the Flash player installed, you can use the link in your study invite email to return to this page.

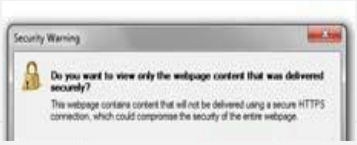
Enable Javascript
Javascript must be enabled in your web browser for the video to appear. Complete the steps for your web browser on the Google website and return to this page.

Check if YouTube works
Go to the YouTube website and try playing a few videos. If the videos work there, they should also work on the study website.

Try a different web browser or different computer
If your computer has a second web browser, you can try it with this site and see if the video works. Alternatively, try a different computer if you have access to one.

Internet-based GP Questionnaire

If a **pop-up window** appears like the one below please click **no** to enable you to watch the video.



Have you previously participated in any of our Curtin Health Innovation Research Institute (CHIRI) e-studies (Referral Writer Study, Discharge Summary Study, Prostate Cancer Study & Breast Cancer Study)?

- Yes
- No

About you

What is your gender?
- Male
- Female

What is your age in years?

GP training

Place of graduation (primary medical degree)
University
Country
City

What year did you graduate from medical school?

How many years have you been practising as a GP?

Are you a GP registrar?

- No
- Yes

Do you hold FRACGP?
- No
- Yes

Your practice

State
- New South Wales
- Queensland
- Victoria
- South Australia
- Tasmania
- Western Australia
- Australian Capital Territory
- Northern Territory

Internet-based GP Questionnaire

Name of city/town

Select from the list the most appropriate description of where your practice is located by rural, remote and metropolitan area classification (RRMA)

- Capital
- Other metropolitan
- Large rural
- Small rural
- Other rural
- Remote centre
- Other remote

Select from the list the most appropriate description of where your practice is located according to the Australian Standard Geographical Classification (ASGC) remoteness structure

- Major cities
- Inner regional
- Outer regional
- Remote
- Very remote

How many GPs are in your practice?

Is your major practice accredited?

- No
- Yes

What is your position in the practice?

- Principal
- Non-principal
- Other (please describe)

How many general practice sessions you do per week? (1 session = approx 4 hours)

How many patients do you see per week?

- less than 100
- 100–149
- 150–199
- more than 199

How many direct patient care hours do you work per week?

- less than 11
- 1–20
- 21–40
- 41–60
- more than60

Do you conduct any of your consultations in a language other than English?

- No
- Yes, less than 25% of consultations
- Yes, 25–50% of consultations
- Yes, more than 50% of consultations

Consultation instructions

There are six patient/actor-GP consultations to view. Please treat this consultation as if a patient has come to your clinic. Take notes if you wish (you can download partly completed Patient Health Summaries and Physical Examination pro-forma below, or at each consultation). Your progress through the survey is saved after each consultation. If for some reason you have problems viewing a video, you will be able to view it again in this survey.

After viewing each consultation, decide what you would do with this patient if they had come to you. You will be given three options—to refer the patient to a specialist, prescribe something to the patient, or send the patient for a test (you can chose more than one option). For any of

these options, you will need to fill out a form (referral letter, test order form or prescription sheet), as you normally would in practice, and these will be available in subsequent pages of the survey (online).

Patient Health Summary pro-forma downloads
Patient health summary consultation one
Patient health summary consultation two
Patient health summary consultation three
Patient health summary consultation four
Patient health summary consultation five
Patient health summary consultation six

Physical Examination pro-forma downloads
Doctor's exam consultation one
Doctor's exam consultation two
Doctor's exam consultation three
Doctor's exam consultation four
Doctor's exam consultation five
Doctor's exam consultation six

Consultation 1: Mr James Spears, age 58 years

Download:
1. Patient health summary consultation one (pdf)
2. Doctor's exam consultation one (pdf)

If a **pop-up window** appears, please click **no** to enable you to watch the video.

Adobe Flash plugin version 9.0.115 or later required for video playback.

Download the Adobe Flash player to play the consultation video.

What is your differential diagnosis?

Your decision (multiple choices can be selected with each management following in subsequent pages).
☐ Refer to a specialist ☐ Prescribe something ☐ Order tests

Internet-based GP Questionnaire

☐ Health advice

Would you prescribe something? If so, what would you prescribe?

Would you refer the patient? If so, to whom?

Would you order tests? If so, which tests?

Consultation 3: Mrs Margaret Howard, age 45 years

Download:
1. Patient health summary consultation three (pdf)
2. Doctor's exam consultation three (pdf)

Your decision (multiple choices can be selected with each management following in subsequent pages).
☐ Refer to a specialist ☐ Prescribe something ☐ Order tests
☐ Health advice

Would you prescribe something? If so, what would you prescribe?

Would you refer the patient? If so, to whom?

"Would you order tests? If so, which tests?"

Consultation 2: Mr David Simpson, age 60 years

Download:
1. Patient health summary consultation two (pdf)
2. Doctor's exam consultation two (pdf)

Internet-based GP Questionnaire

If a **pop-up window** appears, please click **no** to enable you to watch the video.

Adobe Flash plugin version 9.0.115 or later required for video playback.

Download the Adobe Flash player to play the consultation video.

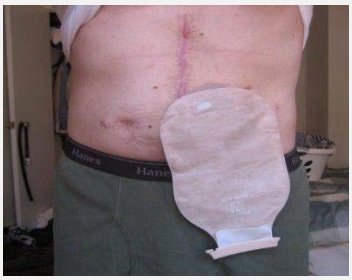


Image correlating to the symptom mentioned above by the patient.

Your decision (multiple choices can be selected with each management following in subsequent pages).
☐ Refer to a specialist ☐ Prescribe something ☐ Order tests
☐ Health advice

Would you prescribe something? If so, what would you prescribe?

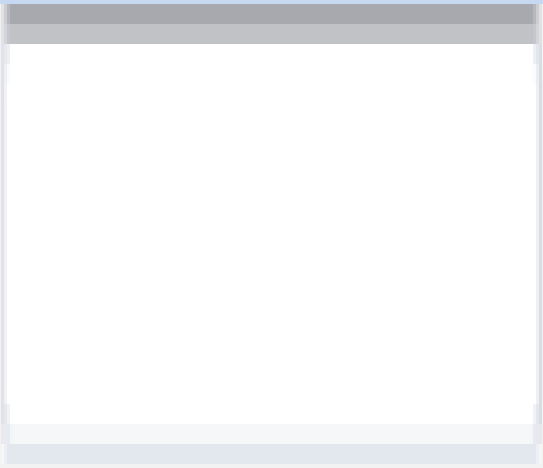
Would you refer the patient? If so, to whom?

Would you order tests? If so, which tests?

Consultation 4: Ms Doreen Furby, age 54 years

Download:
1. Patient health summary consultation four (pdf)
2. Doctor's exam consultation four (pdf)

Internet-based GP Questionnaire



If a pop-up window appears, please click no to enable you to watch the video.

Download the Adobe Flash player to play the consultation video.

Your decision (multiple choices can be selected with each management following in subsequent pages).
☐ Refer to a specialist ☐ Prescribe something ☐ Order tests
☐ Health advice

Would you prescribe something? If so, what would you prescribe?

Would you refer the patient? If so, to whom?

Would you order tests? If so, which tests?

****Please proceed to the next page****

Remuneration

Are you registered with the Australian Taxation Office to charge GST?
○ Yes, I have an ABN and I am registered to charge GST
○ No, I do have an ABN and I am not registered to charge GST
○ No, I do not have an ABN

Appendix 6.6: Actor Consent Form for GP Video Vignette Study

Talent release form

Curtin University

Curtin University
7 Parker Place, Technology Park
Bentley 6102, WA

Telephone +61 8 9266 9213
Facsimile +61 8 9266 2508
Email: l.ngune@curtin.edu.au
Web curtin.edu.au

Project ID: HR42_2012

Project Name: Colorectal Cancer Study

Curtin University
Talent release form for images, video and audio

I hereby give approval for my image and voice to be used by Curtin University for any promotional use with no advertising for a period not exceeding five years (60 months) from the date below.

I understand that Curtin University will not use any images of me in an inappropriate manner.

Name of project/event you are participating in: ……

Talent name:……

Signature:……

Date:……

Contact details Phone:……

Mobile:……

Email:……

Work address:……

……

……

Signed on behalf of Curtin University.

Signature:……

Date:……